# EXHIBIT 4

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| **DePuy Mitek, Inc.**<br>**a Massachusetts Corporation**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**Arthrex, Inc.**<br>**a Delaware Corporation and**<br><br>**Pearsalls Ltd.**<br>**a Private Limited Company**<br>**of the United Kingdom**<br><br>**Defendants.** | ) | **Civil No. 04-12457 PBS** |

**DePuy Mitek's Response to Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Concise Statement of Material Facts in Support of Their Motion for Summary Judgment of Infringement**

**Defendants Fact 1:**

Plaintiff DePuy Mitek, a Massachusetts corporation, and a Johnson & Johnson company, makes and sells medical products. Ex. 17.

**DePuy Mitek's Response to Defendants Fact 1:**

Undisputed.

**Defendants Fact 2:**

Defendant Arthrex, a privately held Delaware corporation, develops and sells medical products in the field of arthroscopic surgery. FiberWire suture and its related products TigerWire and FiberStick ("collectively "FiberWire") are among those products and are the ones accused of infringement of U.S. Patent No. 5,314,446 ("the '446 patent"). Ex. 16.

**DePuy Mitek's Response to Defendants Fact 2:**

Undisputed.

**Defendants Fact 3:**

Defendant Pearsalls, a United Kingdom company, is a braid manufacturer which makes the braids that eventually become FiberWire suture.

**DePuy Mitek's Response to Defendants Fact 3:**

Disputed to the extent that Arthrex suggests that Pearsalls is just a "braid manufacturer." Otherwise undisputed.

**Defendants Fact 4:**

Ethicon, a Johnson & Johnson company, is related to DePuy Mitek and the original owner of the '446 patent. Ex. 18.

**DePuy Mitek's Response to Defendants Fact 4:**

Disputed to the extent that the "original owners" were the inventors, otherwise undisputed.

**Defendants Fact 5:**

In 2001, Arthrex introduced a new suture, called FiberWire, for the orthopedic surgery market. Ex. 1 at 31:2-5.

**DePuy Mitek's Response to Defendants Fact 5:**

Denied to the extent the term "new" is undefined, and it is not clear in what way Arthrex means "new." Based on the information available to it, Mitek admits that before 2001, Arthrex did not sell a suture called FiberWire, and Arthrex introduced FiberWire in 2001. Denied that Arthrex's citation supports the position.

**Fact 6:**

FiberWire was so new and revolutionary that it spawned a new category of suture called "high-strength" suture. Ex. 2 at 2; Ex. 4 at 146:7-14.

**DePuy Mitek's Response to Defendants Fact 6:**

Denied. The phrase "new and revolutionary" is vague and ambiguous. Arthrex's evidence does not support this factual assertion. Arthrex's evidence only indicates that Arthrex was the first company to sell a "high strength" suture. Arthrex's evidence does not establish any causation between the sale of any "new and revolutionary" FiberWire and the creation of a new category of suture.

**Defendants Fact 7:**

FiberWire suture was the first "high-strength" suture introduced into the market. Ex. 2 at 2; Ex. 4 at 146:7-14.

**DePuy Mitek's Response to Defendants Fact 7:**

Undisputed.

**Defendants Fact 8:**

FiberWire was more than twice as strong as the sutures conventionally used in orthopedic surgery, including Ethibond, the leading suture for the orthopedic market sold by Ethicon. Ex. 2 at 8.

**DePuy Mitek's Response to Defendants Fact 8:**

Denied as vague as to the type of "strength" is undefined. Denied based on lack of evidentiary support. Arthrex's evidence does not show that FiberWire is twice as "strong" as Ethibond. For example, size 3-0 FiberWire has a knot strength of 2.60 Kg and size 3-0 Ethibond has a knot strength of 2.06 Kg (Arthrex Ex. 2 at 8).

**Defendants Fact 9:**

FiberWire obtains its strength because it contains ultra high molecular weight polyethylene ("UHMWPE"), one of the strongest synthetic materials ever created. Ex. 3 at § 1.

**DePuy Mitek's Response to Defendants Fact 9:**

Denied. Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. Mitek further objects to the admissibility of this exhibit under authenticity grounds under FED.R.EVID. 901. The term "strength" is vague and ambiguous. FiberWire does not obtain its "strength" from just UHMWPE. Don Grafton, Arthrex's developer of FiberWire, testified at his deposition that knot tie down, which he defined as related to knot strength (Mitek Ex. 1 at 26:14-27:6), would be poor with a 100% UHMWPE suture (*id.* at 26:14-31:1; 52-53). Furthermore, Arthrex's 234 patent states that "[o]ne of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema and Spectra. However, this material, while stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical application" (Mitek Ex. 2 at 1:13-21). Also, Dr. Brookstein has opined that FiberWire's various "strength" characteristics are not due to just UHMWPE (Mitek Ex. 3 at ¶¶19, 20, 38, 39). Further, Mr. Grafton testified that a braid of just UHMWPE could not hold a knot (Mitek Ex. 1 at 46:10-15). Denied that Arthrex has proven that the ultra high molecular weight polyethylene is one of the strongest synthetic materials ever created.

**Defendants Fact 10:**

After seeing the impact of FiberWire, DePuy Mitek realized that without the introduction of its own high strength suture, it would not be able to meet its sales targets. Ex. 5.

**DePuy Mitek's Response to Defendants Fact 10:**

Denied, as the factual support does not support the factual averment. The document refers to "business plan objective" and does not refer to sales targets as Arthrex fact suggests. Admitted that Mitek lost sales to Arthrex's FiberWire product.

**Defendants Fact 11:**

DePuy Mitek's original idea was to introduce a "me too" suture that mimicked FiberWire. Ex. 5. In late 2004, DePuy Mitek introduced its own high strength suture called Orthocord, which also includes UHMWPE. Ex. 6.

**DePuy Mitek's Response to Defendants Fact 11:**

The first sentence is denied. The terms "mimicked" and "original" are vague and ambiguous. This fact is denied to the extent it suggests that DePuy Mitek copied the design of Arthrex's FiberWire. Orthocord has a different design. Disputed with respect to "late 2004" being vague and ambiguous.

**Defendants Fact 12:**

Shortly before filing this lawsuit, the '446 patent was assigned from Ethicon to DePuy Mitek. Ex. 7. In this lawsuit, DePuy Mitek alleges that defendants infringe claims 1, 2, 8, 9 and 12 of the '446 patent ("the asserted claims").

**DePuy Mitek's Response to Defendants Fact 12:**

Undisputed.

**Defendants Fact 13:**

Neither Ethicon nor DePuy Mitek has never made a commercial product covered by the '446 patent. The '446 patent is a paper patent. Ex. 9.

**DePuy Mitek's Response to Defendants Fact 13:**

Mitek cannot answer with respect to the first sentence because it has three negatives "neither, nor, and never," and it is not clear what Arthrex intends by this statement. The term "paper patent" is not defined and there is no such "paper patent" doctrine recognized by law. To the extent Arthrex is suggesting that the invention has not been commercialized, Arthrex is wrong because FiberWire is an infringement (Mitek Ex. 3 at ¶¶16-64; Mitek's Memorandum in Support of Its Motion for Summary Judgment and exhibits cited therein)

**Defendants Fact 14:**

Ethicon began the work that led to the '446 patent in 1988. As explained by inventor Steckel, this work was part of a larger project designed to examine possible suture improvements. Ex. 19 at 103:23-104:17.

**DePuy Mitek's Response to Defendants Fact 14:**

Undisputed.

**Defendants Fact 15:**

At the time, a standard braided suture was Ethibond, a suture made entirely of PET polyester, which was braided to form the suture. Ex. 4 at 135:4-7.

**DePuy Mitek's Response to Defendants Fact 15:**

Denied because the asserted fact is vague regarding "at the time" and the field of use is not specified. Arthrex's supporting evidence explains the construction of Ethibond but not anything with respect to being a standard during any particular time (Arthrex Ex. 4 at 135:4-7).

**Defendants Fact 16:**

Dr. Steckel's idea was to braid together two different substances, one to maintain as much of the strength of the suture as possible and the other to enhance the pliability (that is, bendability) and handleability of the suture. As Dr. Steckel explained, the goal was to produce a suture which maintained the strength of Ethibond (made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 19 at 103:23-104:17.

**DePuy Mitek's Response to Defendants Fact 16:**

Denied because Dr. Steckel's "idea" and "goal" was not so limited, and Arthrex's citations do not support such a limitation on Dr. Steckel's "idea" and "goal." Further, Dr. Steckel did not testify that he had only one idea and one goal. For example, in the 446 Patent, Dr. Steckel explains that his concept was broader and included many other concepts (Arthrex Ex. 8 at 2:40-62; 3:40-51; 4:9-14). Arthrex's fact takes Dr. Steckel's testimony out of context and mischaracterizes Dr. Steckel's testimony and omits the testimony on the following pages of his deposition where he testified that his ideas and goals were not so limited:

Q. -- was it an object of the patent to try and produce a suture stronger than Ethibond?
A. (Witness reviews document.) I would say since we're clearly looking at aromids, I would say the answer was yes.

Q. And that was by using an aromid?
A. No. That would be one way of doing it.
Q. Is there anything --
A. We were certainly looking at fiber. We were certainly considering fibers that offer higher tensile strength than -- than strictly PET.
Q. And that was the aromids?
A. That was one of -- that was one example.
Q. Is there anything else?
A. Well, the patent describes generic classes of polymers, and the high strength aspect of it has more to do with how those polymers were processed. So, any of those polymers that are listed, you know, could be processed in a high strength form or a medium-strength form or a low-strength form.
Q. When you're saying, "these," which ones are you talking about?
A. I'm referring to the polymers listed in the claims.
Q. All of them?
A. All of those can be processed to get a range of low, medium, or relatively high strength.

(Mitek Ex. 4 at 105:17-106:24) (objections omitted).

**Defendants Fact 17:**

Ethicon built and test heterogeneous braids, made of PTFE and PET, by February 2, 1989. None of these braids, however, were sterilized. Ex. 19 at 225:5-8.

**DePuy Mitek's Response to Defendants Fact 17:**

Mitek admits the first sentence of Arthrex's fact #17. Mitek denies the second sentence. Arthrex's cited evidence only states that Dr. Steckel "believe[d]" that the braids were not sterilized at that point in the process, not that the braids were not sterilized (Arthrex Ex. 19 at 225:5-8).

**Defendants Fact 18:**

Ethicon never built a sterilized surgical suture that included all the limitations of the asserted claims before the filing date of the '446 patent. Ex. 10 at 345:7-10.

**DePuy Mitek's Response to Defendants Fact 18:**

Denied. Arthrex cites to Dr. Hermes' testimony, but Dr. Hermes said that "I don't know" whether the braids built by Ethicon were sterilized (Arthrex Ex. 10 at 345:14). Arthrex's cited evidence does not support the factual assertion that "Ethicon never built a sterilized surgical suture that included all the limitations of the asserted claims before the filing date of the '446 patent." Also, denied based on Dr. Hermes testimony and Dr. Steckel's work (Mitek Ex. 5 at ¶¶31-43).

**Defendants Fact 19:**

During his development work, Dr. Steckel observed that the prototype composite braid "ranked better than the silk and Ethibond in knot tie-down even without a coating." Ex. 21 at DMI 2666.

**DePuy Mitek's Response to Defendants Fact 19:**

Undisputed that Dr. Steckel made this observation but denied to the extent that Arthrex suggests that Dr. Steckel ever intended to exclude coatings. Dr. Steckel testified and explained otherwise in the 446 Patent (Mitek Ex. 4 at 308:8-11; Arthrex Ex. 8 at 6:5-18).

**Defendants Fact 20:**

Dr. Steckel knew during the development work that led to the '446 patent that UHMWPE had great strength. Ex.5 (to *Markman* Brief) at 190:12-191:3.

**DePuy Mitek's Response to Defendants Fact 20:**

Denied because vague as to type of "strength" and "great." Mitek admits that Dr. Steckel testified as he did on pages 190:12-191:13 of his deposition (Arthrex Ex. 5 to *Markman* Brief).

**Defendants Fact 21:**

Ethicon filed the application that led to the '446 patent on February 19, 1992, three years after Dr. Steckel tested the braids. Ex. 8 at cover page.

**DePuy Mitek's Response to Defendants Fact 21:**

Denied because "the braids" are undefined and there is no antecedent basis. Undisputed that Ethicon filed the application that led to the '446 patent on February 19, 1992, three years after Dr. Steckel tested the braided sutures that are discussed in his February 1989 lab notebook entry.

**Defendants Fact 22:**

The specification of the '446 patent begins with a summary of prior suture development, explaining that multi-filament braided sutures were developed to improve suture pliability compared to monofilament, unbraided sutures. Ex. 8 at col. 1, ll. 5-25.

**DePuy Mitek's Response to Defendants Fact 22**

Denied. Mitek admits only that the 446 Patent (Arthrex Ex. 8) states what it states on column 8, lines 5-25, and that statement is not present in the cited evidence.

**Defendants Fact 23:**

The specification cautioned that mechanisms, such as coating, will adversely affect braid mobility and explained that "the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid." Ex. 8 at col. 1, ll. 26-29.

**DePuy Mitek's Response to Defendants Fact 23:**

Denied. The citation from the 446 Patent does not discuss "braid mobility" and that term is not defined here. Further, no effects of coating on "braid mobility" are discussed in the cited evidence. Further, this "fact" mischaracterizes the '446 patent and takes the quoted passage out of context (Arthrex Ex. 8 at 1:16-29). Denied to the extent that Arthrex tries to make a universal statement about all coatings that is not supported by the evidence and not true. The 446 patent recognizes that not all coatings will cause the fibers or yarns to adhere to one another (Arthrex Ex. 8 at 6:11-13).

**Defendants Fact 24:**

The first example presented in the specification is coating, which "improve[s] handling properties," but at the expense of braid pliability. Ex. 8 at col. 1, ll. 29-31.

**DePuy Mitek's Response to Defendants Fact 24:**

Denied. The cited evidence does not say anything about "the expense of braid pliability." Further, denied because the term "first example" is undefined. The first example discussed in the 446 Patent is a "braided multifilament" (Arthrex Ex. 8 at 1:6). This "fact" mischaracterizes the '446 patent and takes the quoted passage out of context. The 446 patent recognizes that not all coatings affect braid pliability (*id.* at 6:5-17).

**Defendants Fact 25:**

The specification suggests that while a braid made entirely of "highly lubricious polymers" can be used to make a highly pliable braid, such a braid "will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments." Ex. 8 at col. 2, ll. 22-28.

**DePuy Mitek's Response to Defendants Fact 25:**

Denied. Mitek admits that the cited passage states that:

> If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

(Arthrex Ex. 8 at 2:22-28). The passage says that "in most cases," not all cases, the braid will be relatively weak and unusable. Also, it refers to "highly lubricous polymers [that] are used in thetraditional manner" not just "highly lubricous polymers. Mitek denies that this paragraph has the meaning that Arthrex subscribes to it (Mitek Ex. 5 at ¶¶49-54).

**Defendants Fact 26:**

This theme that lubricious polymers are too weak for suture usage is repeated when the specification explains that a "volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid." Ex. 8 at col. 4, ll. 50-54.

**DePuy Mitek's Response to Defendants Fact 26:**

Denied. Mitek disputes that the 446 Patent has such a theme (Arthrex Ex. 8 at 2:40-62; 3:40-51; 4:10-14, expressing broader concepts and combinations of materials). The 446 Patent never says that "lubricious polymers are too weak for suture usage" and in fact teaches embodiments that use lubricous polymers (*id.* at 4:9-32). Also, Arthrex's citation is to a "most preferred embodiment," not all embodiments (*id.* at 4:41-59).

**Defendants Fact 27:**

The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made of two different fiber forming materials which exhibits "improved pliability and handling properties . . . without appreciably sacrificing" [the suture's] physical properties," (Ex. 8 at col. 2, lines 31-37), namely its "physical strength and knot security." Ex. 8 at col. 2, l. 66. This proposed solution is repeated throughout the specification. Ex. 8 at col. 2, ll. 62-66; col. 6, ll. 7-8.

**DePuy Mitek's Response to Defendants Fact 27:**

Denied as vague. The fact does not say what the "proposed solution" that it references is for. Denied to the extent that Arthrex suggests that the 446 Patent has only "one solution" and not many embodiments of a range of properties from dissimilar yarns (Arthrex Ex. 8 at 2:40-66; 3:40-51; 4:11-13; 4:35-36), and Arthrex cites to preferred and most preferred embodiments. Denied as Arthrex picks and selects citations from the 446 Patent and ignores the totality of its teachings. Denied to the extent Arthrex suggests that the 446 patent is limited to this preferred embodiment (*id.* at 2:40-66; 3:40-51). Denied with respect to "repeated" as Arthrex cites to the same citation and alleges that the same citation is a repeat (*id.* at 2:66) and its other alleged repeated citation does not support Arthrex's statement (*id.* at 6:7-8). Denied with respect to Arthrex's characterization of the 446 patented invention (Mitek Ex. 3 at ¶¶25, 35; Mitek Ex. 5 at ¶¶49-54).

**Defendants Fact 28:**

The '446 patent specifically refers to "pliability" in connection with "resistance to bending," (Ex. 8 at col. 1, ll. 11-15, 24) and "bending rigidity," (Ex. 8 at col. 6, ll. 44-45, col. 8 at Table, ll. 44-46), which are the inverse of pliability.

**DePuy Mitek's Response to Defendants Fact 28:**

Undisputed.

**Defendants Fact 29:**

A handling property specifically identified in the '446 patent is "knot tie down." Ex. 8 at col. 6, ll. 7-8.

**DePuy Mitek's Response to Defendants Fact 29:**

Denied to the extent Arthrex has not defined what it means by "knot tie down" in this fact, and the term has been used differently (Mitek Ex. 1 at 26:14-27:6; Arthrex's Ex. 29). Mitek admits that column 8, lines 7-8 of the 446 Patent refers to "handleability and knot tiedown performance of the braid" but denies that it states that knot tie down is a handling property.

**Defendants Fact 30:**

The '446 patent relies on what is called the "rule of mixtures" to attempt to demonstrate that this combination is an improvement in the art. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength. Ex. 8 at col. 8, ll. 22, 35 and 38.

**DePuy Mitek's Response to Defendants Fact 30:**

This fact is vague because "this combination" is vague and ambiguous. Mitek admits that examples of a "most preferred embodiment" of PTFE and PET are discussed with reference to the rule of mixtures and some properties, but not all properties, of this most preferred embodiment are discussed with reference to the rule of mixtures (Arthrex Ex. 8 at 4:41-44; 6:59-8:35). Denied as the 446 does not make a point about "weak" materials and does specify any material as being a "weak" material. Further, the cited references do not state "highly pliable materials." The PTFE and PET materials are described differently (*id.* at 4:9-40). Denied to the extent Arthrex suggests that the 446 patent is limited to a preferred embodiment.

**Defendants Fact 31:**

The specification also discusses the use of coating on sutures. It explains that coating, if desired, can be added "to further improve the handleability and knot tiedown performance of the braid." The specification also states that it is better if coating is not used, explaining that if the braid "possesses a significant [amount] of the lubricious yarns, the conventional coating may be eliminated saving expense as well as the associated braid stiffening." Ex. 8 at col. 6, ll. 5-17.

**DePuy Mitek's Response to Defendants Fact 31:**

Undisputed that the 446 Patent "specification discusses the use of coating on sutures," but denied with reference to the term "also" because it has no antecedent basis in the fact. Undisputed that the 446 Patent states that: "If desired, the surface of the heterogeneous braid can be coated to further improve knot tiedown performance of the braid" (Arthrex Ex. 8 at 6:5-8). Mitek disputes the remaining averments of Fact 31. The specification does not state it is "better" if coatings are not used. The 446 patent states that coatings can be used or not used (*id.* at 6:5-17).

**Defendants Fact 32:**

Seven polymers (PTFE, FEP, PFA, PVDF, PETFE, PP and PE) are identified as the yarns that are included for lubricity so as to improve the overall pliability of the braid. Ex. 8 at col. 4, ll. 11-27.

**DePuy Mitek's Response to Defendants Fact 32:**

Undisputed that the 446 Patent identifies the seven polymers PTFE, FEP, PFA, PVDF, PETFE, PP, and PE. Undisputed that in preferred embodiments, these seven yarns are identified as "lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid" (Arthrex Ex. 8 at 4:11-14). Denied to the extent that Arthrex implies that that the seven polymers are stated as only being for lubricity to improve the overall pliability of the braid" and ignores the "preferred embodiment" language, the "or compliance, and surface lubricity" language, and the broader teachings of the 446 Patent (*id.* at 2:40-63; 3:40-51).

**Defendants Fact 33:**

Three materials, PET, nylon and aramid, are identified as the ones that could be used for improving the strength of the braid. Ex. 8 at col. 4, ll. 35-40. The term PE is never associated with the "strength" yarns.

**DePuy Mitek's Response to Defendants Fact 33:**

Undisputed that the 446 Patent states that "in a more preferred embodiment, the lubricating yarns of the firs set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid." Denied to the extent that Arthrex is saying that PET, nylon, and aramid are the only "ones" that could be used for improving strength (Mitek Ex. 4 at 105:17-106:24; Mitek Ex. 3 at ¶¶18,19,36, 37). Denied to the extent Arthrex ignores the "more preferred embodiment" language and alleges that PET, nylon, and aramid are only identified as providing strength (Arthrex Ex. 8 at 4:33). Also, denied as there are no "strength yarns" defined in the 446 Patent, and Arthrex has not defined the antecedent for "the strength yarns." Denied as one of ordinary skill in the art reading the 446 Patent would understand that UHMWPE is disclosed and would be understood to provide certain strength attributes (Mitek Ex. 5 at ¶¶44-59), and strong yarns of PP and PVDF are also disclosed (Mitek Ex. 3 at ¶¶36-38). Further, Arthrex's expert, Dr. Mukherjee, admits that all *polypropylene* fibers are disclosed (Mitek Ex. 6 at 297:9-15), and ultra high molecular weight polypropylene has ultra high molecular weight forms (Ex 11 to Mitek Ex. 3 at 1:11-15; 2:7-14).

**Defendants Fact 34:**

Claim 1 of the '446 patent is to a surgical suture "consisting essentially of" a heterogeneous braid of a first and second set of yarns in a sterilized and braided construction. Ex. 8 at claim 1.

**DePuy Mitek's Response to Defendants Fact 34:**

Undisputed.

**Defendants Fact 35:**

The remainder of the asserted claims ultimately depend from claim 1. Ex. 8 at claims 2, 8, 9, 12.

**DePuy Mitek's Response to Defendants Fact 35:**

Undisputed.

**Defendants Fact 36:**

Claim 1 defines the first set of yarns as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE – the same materials identified in the specification as being pliable and lubricious. The claim defines the second set of yarns as one of PET, nylon and aramid – the same materials identified in the specification as being added for improving the strength of the braid. Ex. 8 at claim 1.

**DePuy Mitek's Response to Defendants Fact 36:**

Denied. PTFE, FEP, PFA, PVDF, PETFE, PP and PE are not identified in the 446 Patent as being "pliable." Rather, they are identified in preferred embodiments as lubricating yarns, not pliable yarns (Arthrex Ex. 8 at 4:11-12). Also, these are preferred embodiments and not limiting properties (*id.*). Denied to the extent that Arthrex is saying that PET, nylon, and aramid are the only "ones" that could be used for improving strength. Denied to the extent Arthrex ignores the "more preferred embodiment" (*id.* at 4:33) language and alleges that PET, nylon, and aramid are only identified as providing strength (Mitek Ex. 3 at ¶¶18, 19, 36-38; Mitek Ex. 5 at ¶¶44-59). Denied as the 446 Patent provides a broader description of properties and one of ordinary skill in the art would understand that to be so (Arthrex Ex. 8 at ¶¶2:40-63; 3:40-51; Mitek Ex. 3 at ¶¶25, 35).

**Defendants Fact 37:**

As the application for the '446 patent was originally filed, there were two sets of claims – one set for heterogeneous braids and a second set for surgical sutures made from heterogeneous braids. Ex. 22.

**DePuy Mitek's Response to Defendants Fact 37:**

Undisputed that the '446 Patent as originally filed had two sets of claims one of which was for heterogeneous braids. Denied that the other set was for "surgical sutures made from heterogeneous braid." The 446 Patent original "surgical suture" claims do not recite that they were "made from heterogeneous braids" (Arthrex Ex. 22 at DMI00033-35).

**Defendants Fact 38:**

Ethicon was required to elect which set of claims it wanted to prosecute. The election was required because the patent examiner observed that they were distinct sets of claims where one set – the heterogeneous braid claims – were an intermediate product that could be used to make surgical sutures (the second set of claims) as well as other products. Ethicon elected to pursue the surgical suture claims. Ex. 23.

**DePuy Mitek's Response to Defendants Fact 38:**

Undisputed that Ethicon was required to elect which set of claims it wanted to prosecute. Undisputed that Ethicon elected to pursue the surgical suture claims. Undisputed that the patent examiner observed that the heterogeneous braid and surgical suture claims were patentably distinct. Undisputed that the heterogeneous braid was deemed to be useful as a fishing line and the inventions were deemed patentably distinct since there is nothing in the record to show them to be obvious variants (Arthrex Ex. 23). Denied to the extent Arthrex states otherwise and contrary to the statements by the Examiner (Arthrex Ex. 23).

**Defendants Fact 39:**

As originally filed, the first suture claim required only that the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact. The specific materials were not part of the claim and it did not include the "consisting essentially of" limitation. Ex. 22.

**DePuy Mitek's Response to Defendants Fact 39:**

Denied. The phrase "first suture claim" is vague and ambiguous. The "first suture claim" requires more than that "the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact" (Arthrex Ex. 22 at DMI000035 at claim 21, depending on claim 1). For example, the claim recites that "each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material" (*id*.). Denied as "specific materials" is undefined in Arthrex's fact, and the claim recited "filaments of a fiber-forming material" are more specific than the yarns recited.

**Defendants Fact 40:**

In the first Office Action, the examiner rejected the suture claims based on U.K. patent application no. 2,218312A to Burgess ("the Burgess application") (Ex. 8 to *Markman* Brief).

**DePuy Mitek's Response to Defendants Fact 40:**

Undisputed.

**Defendants Fact 41:**

The Burgess application disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester. Ex. 8 (to *Markman* Brief). The examiner rejected the suture claims, explaining that the requirements for fishing line were similar to those of suture. Ex. 23 at 4.

**DePuy Mitek's Response to Defendants Fact 41:**

Denied. The Burgess application does not disclose "a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester" (Mitek Ex. 5 at ¶59). Rather, Burgess discloses a "braided construction" but does not specify what the construction is or how the materials are used in that construction (*id.*). For example, Burgess does not disclose whether the "braided construction" is all one type of materials in the sheath and the other material in the core, which are not in direct intertwining contact or another construction (*id.*). Arthrex's expert Dr. Mukherjee admits that a core/sheath arrangement with all one material in the sheath and all another material in the core is a "braided construction" (Mitek Ex. 6 at 217:12-14; 218:23-219:3). Further, Arthrex's Exhibit 23 does not say that the Burgess application discloses "a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester." Arthrex's Exhibit 23 refers to a "braided construction" of "filaments" not yarns.

**Defendants Fact 42:**

In distinguishing the '446 patent from the Burgess application, Ethicon responded that because of its braided construction, "the fishing line of Burgess would have poor knot strength properties." [Emphasis in original.] Ethicon explained that the Burgess braid combination would have poor knot strength properties because it included UHMWPE. Ethicon stated that UHMWPE "gives the line minimal stretchability." [Emphasis in original.] Ex. 24 at 2.

**DePuy Mitek's Response to Defendants Fact 42:**

Undisputed that Burgess was distinguished as nonanalogous art. Denied to the extent that Arthrex takes isolated statements, characterizes them as the "response," and ignores other statements such as that fishing line and sutures have dissimilar property requirements and "there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines" (Arthrex Ex. 24 at DMI000196). Denied as the response does not refer to the "Burgess braid combination" and attributes nothing to a "braid combination" (Arthrex Ex. 24 at DMI000195). Denied that Arthrex implies that the response refers to UHMWPE yarns, when it refers to "braid filaments" and "thread" of ultra high molecular weight PE.

**Defendants Fact 43:**

Ethicon further explained that "although this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties." [Emphasis in original.] Ethicon concluded that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art. Ethicon also told the Patent Office that "[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture." Ex. 24 at 3-4.

**DePuy Mitek's Response to Defendants Fact 43:**

Undisputed that in an office action response, Ethicon stated that "[a]lthough this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties" (Arthrex Ex. 24 at 3-4). Ethicon did not "conclude[d] that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art" (*id.* at 4). Ethicon stated that "[i]n view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines" (*id.*). Ethicon did not say "[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture." Rather, Ethicon said that "[e]ven if [a medical designer] did use the teachings of the fishing line art to modify a suture, then he would inevitably design an unacceptable suture" (*id.* at 4-5).

**Defendants Fact 44:**

Later during prosecution, Ethicon made two amendments to the claims. First, it abandoned the broad claims that required only that that braid be made of two dissimilar materials. Ex. 25 at 1. The allowed claims were limited to so that the dissimilar materials had to be from the group of specifically-named materials. Ex. 25.

**DePuy Mitek's Response to Defendants Fact 44:**

Denied. The originally filed claims required more than "only that that [sic] braid be made of two dissimilar materials (Arthrex Ex. 22 at DMI000033-35). Denied that Mitek "made two amendments to the claims" and "abandoned the broad claims." That fact is not supported by the citation. Also, the phrase "were limited to so that the dissimiliar materials had to be from the group of specifically-named materials" is vague, ambiguous, and unintelligible and not defined as to what group of materials it refers. Denied to the extent that Arthrex implies that the claim is limited in scope in some fashion to some specifically recited materials and no equivalents are available.

**Defendants Fact 45:**

The first set of yarns are from a group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The second set of yarns were from the group consisting of PET, nylon and aramid. Ex. 25.

**DePuy Mitek's Response to Defendants Fact 45:**

Denied to the extent Arthrex ignores that the yarns are composed of a plurality of filaments of a first fiber-forming material selected from a group consisting of certain select materials (Arthrex Ex. 25 at DMI0000258).

**Defendants Fact 46:**

The preamble of the claims was also amended to change the term "comprising" to "consisting essentially of." Ex. 25 at 1.

**DePuy Mitek's Response to Defendants Fact 46:**

Undisputed.

**Defendants Fact 47:**

UHMWPE is a stiff material. It is not a pliable material. Ex. 11 at ¶ 56; Ex. 10 at 306:20-307:4.

**DePuy Mitek's Response to Defendants Fact 47:**

Denied as the cited evidence does not support the factual assertion. Arthrex Ex. 11 at ¶56 does not say that UHMWPE is a "stiff material" and "is not a pliable material." Paragraph 56 refers to a *braid* of UHMWPE that Arthrex had requested be less stiff, not that the *material* is stiff. Also, Ex. 10 does not have pages 306 and 307.

**Defendants Fact 48:**

General purpose PE has been used in sutures and other materials for decades and is established as a general purpose commodity polymer. Ex. 3 at § 1.

**DePuy Mitek's Response to Defendants Fact 48:**

Denied. The term "general purpose PE" and "general purpose commodity polymer" are not defined and therefore vague and ambiguous. DePuy Mitek does not dispute that PE, including UHMW PE, has been used in sutures for decades. Mitek does not dispute that PE including UHMW PE has "general purposes" (Mitek Ex. 3 at ¶40), and PE including UHMW PE are "commodity polymers."

**Defendants Fact 49:**

UHMWPE was introduced as in fiber form in 1985 and is considered a specialized high performance product. Ex. 3 at § 1.

**DePuy Mitek's Response to Defendants Fact 49:**

Denied. Mitek does not dispute that UHMWPE was available in fiber form in 1985. Mitek does not dispute that it was known to use UHMWPE in sutures in the 1980's (Ex. 7 at DMI000159). Ultra high molecular weight polyethylene fibers were known prior to 1985 (*id.*). Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. Mitek further objects to the admissibility of this exhibit under authenticity grounds under Fed.R.Evid. 901. Mitek objects to its admissibility here. Thus, Mitek disputes that Arthrex has evidence to establish its facts. Nevertheless, denied as "specialized high performance product" is not defined. Nevertheless, Mitek disputes that §1 of this exhibit states that UHMWPE "is considered a specialized high performance product."

**Defendants Fact 50:**

General purpose polyethylene and UHMWPE are not substitutes for each other. Ex. 12 (to *Markman* Brief) at 22.

**DePuy Mitek's Response to Defendants Fact 50:**

Denied. The term "general purpose PE" is not defined and therefore vague and ambiguous. The term "substitutes" is vague and ambiguous and, as used, overbroad. UHMWPE is equivalent to PE as used in the 446 patent (Mitek Ex. 3 at ¶¶16-42). Arthrex's supporting citation is a conclusory statement with no support. Arthrex's lack proof that "general purpose polyethylene" and ultra high molecular weight PE are never substitutes for each other. In fact, the 446 Patent refers to "PE" generically (Mitek Ex. 5 at ¶¶44-58; Mitek Ex. 3 at ¶40).

**Defendants Fact 51:**

The key structural characteristics of UHMWPE and general purpose polyethylene, molecular weight and molecular structure very different. Ex. 3 at § 2.

**DePuy Mitek's Response to Defendants Fact 51:**

Denied. Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. Mitek further objects to the admissibility of this exhibit under authenticity grounds under Fed.R.Evid. 901. The term "general purpose PE" is not defined and therefore vague and ambiguous. Both UHMWPE and PE are both polymers made from ethylene (Mitek Ex. 5 at ¶44). Denied as the context of "key structural characteristics are not defined," and the key structural characteristics are that they are both polymers made from ethylene. Denied with respect to "very different" as their molecular structure is not "very different" particularly in comparison to other structures (Mitek Ex. 5 at ¶44). Denied that PE having a molecular weight of "several hundred thousand" (which presumptively includes 999,999 and which Arthrex apparently contends is "general purpose PE") is "very different" from PE having a molecular weight of 1,000,000 (which Arthrex apparently contends is ultra high molecular weight PE.

**Defendants Fact 52:**

UHMWPE has a molecular weight in the range of 1 to 5 million, whereas general purpose PE has a molecular weight in the range of 50,000 to several hundred thousand. Ex. 3 at § 2.

**DePuy Mitek's Response to Defendants Fact 52:**

Denied. Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. The term "general purpose PE" is not defined and therefore vague and ambiguous. Arthrex has no admissible evidence to support this fact. Also, Denied to the extent that Arthrex is relying on an advertising brochure as a technical reference.

**Defendants Fact 53:**

UHMWPE exhibits a much higher degree of crystalline orientation and crystalline content as compared with general purpose polyethylene. Ex. 3 at § 2.

**DePuy Mitek's Response to Defendants Fact 53:**

Denied. Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. The term "general purpose PE" is not defined and therefore vague and ambiguous. Arthrex has no admissible evidence to support this fact. The phrase "much higher" is vague and ambiguous.

**Defendants Fact 54:**

DePuy Mitek's expert, Dr. Hermes' first impression when reading the '446 patent was that it "seem[ed] to teach away from UHMWPE." Ex. 14 (to *Markman* Brief); Ex. 10 at 336:23-23.

**DePuy Mitek's Response to Defendants Fact 54:**

Denied. Arthrex mischaracterizes the quoted passage and takes the testimony out of context. Dr. Hermes testified that his note in which the quoted phrase appears was directed to Dr. Mukherjee's statements in his report that a preferred embodiment of the invention seemed to teach away (Mitek Ex. 8 at 335:19-337:4). Dr. Hermes was not testifying to the overall scope of the 446 patent or that he thought it taught away (*id.*). Further, as Dr. Hermes testified, that was not his "first impression when reading the '446 Patent" (*id.* at 334:4-8; 334:25-335:6). Rather, it was his notes of what Dr. Mukherjee had said in reading Dr. Mukherjee's expert report and it was the *first time he had read Dr. Mukehrjee's report*, not the patent (*id.* at 334:4-8; 334:25-335:6).

**Defendants Fact 55:**

Based on the teachings of the '446 patent, Ethicon's statements in the prosecution history and the differences between general purpose polyethylene and UHMWPE, the term "PE" in the asserted claims of the '446 patent means general purpose polyethylene and does not include UHMWPE. Accordingly, FiberWire does not contain a material from the first set of yarns and does not infringe the asserted claims of the '446 patent literally or by the doctrine of equivalents.

**DePuy Mitek's Response to Defendants Fact 55:**

Denied. Arthrex's "factual" averments is not a fact, but a legal contention. Also, it has not support. The term "PE" as used in the 446 patent includes UHMWPE (Mitek Ex. 5 at ¶¶44-48; Mitek's Markman and Summary Judgment Briefs and Exhibits).

**Defendants Fact 56:**

The specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification and is confirmed by the attorney who prosecuted the application for Ethicon and is consistent with Dr. Steckel's description of his work. Ex. 8 at col. 2, ll. 29 – 37; ll. 62 – 66; col. 4, ll. 11-40; col. 6, ll. 7 – 8; Ex. 8 at 110:14-20; Ex. 8 at 103:23—104:17.

**DePuy Mitek's Response to Defendants Fact 56:**

Denied. This is not a factual averment, but a legal contention. Denied based on Mitek's claim construction briefing and summary judgment briefing and exhibits cited therein. (*see generally* prosecution history distinguishing over certain bioabsorbable yarns and Arthrex Ex. 8 at 2:40-62). Denied that the concept is repeated throughout the specification and that Arthrex's citations support that. Denied as Arthrex has not cited to any of Dr. Steckel's here, and Dr. Steckel did not so limit his work (Mitek Ex. 4 at 102:21-103:9; 105:17-106:24).

**Defendants Fact 57:**

Multiple patents, including patents owned by Ethicon and its expert, and publications (including from Ethicon) indicate that coating affects handleability characteristics of a suture, including knot tie-down. This was also asserted by Ethicon and DePuy Mitek when they developed suture products and was confirmed by several Ethicon and DePuy Mitek witnesses. Ex. 34, col. 1, ll. 14-18; Ex. 35, col. 1, ll. 11-15; Ex. 36, col. 1, ll. 12-15; Ex. 37, col. 1. ll. 19-25; Ex. 29 at 11; Ex. 28 at 525; Ex. 39; Ex. 40; Ex. 4 at 64:12-24; Ex. 41 at 48:11-49:2; Ex. 31 at 167:1-13; Ex. 18 at 295:23-296:7; Ex. 42 at 63:10-23; Ex. 14; Ex. 8 at col. 1, ll. 29-31; col. 6, ll. 5-8. As stated above, the '446 patent also states that coating improves the handling characteristics of the suture, including knot tie-down.

**DePuy Mitek's Response to Defendants Fact 57:**

Denied to the extent that this fact supports the proposition that the specific coating on FiberWire materially affects the basic and novel characteristics of the 446 patent (Mitek Ex. 3 at ¶¶43-62). Denied that any of the citations say anything about the materiality of the effects of FiberWire's coating or other coatings to the claimed invention. Denied to the extent that Arthrex refers to all coatings applied in any matter, and Arthrex is not specific as to any particular coating. Denied as Arthrex's expert, Dr. Burks, the only surgeon to testify on the issue, said he was not sure that he could tell the difference using gloves between coated and uncoated sutures in handleability and knot tie down, and said he could not always tell the difference, and characterized the differences due to coating as "subtle" (Mitek Ex. 9 at 71:21-72:23; 73:9-14; 87:7-13; 88:1-3; 9-10; 96:18-19; 96:24-98:3; 98:15-21). Denied with respect to "patents owned by" Mitek's expert, as it is not clear that either expert owns any patents that are relevant to this

action and it has not been proven here. Denied as the citation to Arthrex Ex. 36 does not refer to knot tie down. Denied as the citation to Arthrex Ex. 37 refers to knot tie down but not other characteristics. Denied as there is no page 525 to Arthrex's Ex. 28. Denied as Arthrex's Ex. 18 does not have a 295:23-296:7.

**Defendants Fact 58:**

FiberWire contains a coating to improve handling characteristics, including suture slide, knot tying and ease of passing suture through tissue. Ex. 14.

**DePuy Mitek's Response to Defendants Fact 58:**

Denied as Arthrex's expert, Dr. Burks, the only surgeon to testify on the issue, said he was not sure that he could tell the difference using gloves between coated and uncoated sutures in handleability and knot tie down, and said he could not always tell the difference, and characterized the differences due to coating as "subtle" (Mitek Ex. 9 at 71:21-72:23; 73:9-14; 87:7-13; 88:1-3; 9-10; 96:18-19; 96:24-98:3; 98:15-21).

**Defendants Fact 59:**

For the reasons stated above, coating affect the basic and novel characteristics of the asserted claims of the '446 patent and its inclusion in FiberWire precludes infringement of those claims.

**DePuy Mitek's Response to Defendants Fact 59:**

Denied. This is not a fact but an incorrect legal contention (See Mitek's Markman and Summary Judgment briefing and exhibits therein). Arthrex's fact incorrectly states the law. The proper question is whether the coating *materially* affects the basic and novel characteristics of the 446 patent. Denied as Arthrex's expert, Dr. Burks, the only surgeon to testify on the issue, said he was not sure that he could tell the difference with just using gloves between coated and uncoated sutures in handleability and knit tie down, and said he could not always tell the difference, and characterized the differences due to coating as "subtle" (Mitek Ex. 9 at 71:21-72:23; 73:9-14; 87:7-13; 88:1-3; 9-10; 96:18-19; 96:24-98:3; 98:15-21). Even assuming that the basic and novel characteristics are defined as Arthrex has defined them (which they are not) the coating does not materially affect the basic and novel characteristics (Mitek Ex. 3 at ¶¶43-62).

**Defendants Fact 60:**

United States Patent No. 5,318,575 ("the '575 patent") is prior art to the '446 patent. Ex. 15 at cover page; Ex. 8 at cover page.

**DePuy Mitek's Response to Defendants Fact 60:**

Denied. This is not a fact, but a legal contention. Nevertheless, denied as United States Patent No. 5,318,575 ("the '575 patent") is not prior art to the '446 patent (Mitek Ex. 5 at ¶¶31-

43). The 446 inventors actually reduced the claimed invention to practice as early as 1989 (*id.*). Also, the 446 inventors conceived the invention as early as June 1998 (Ex. 7 to Mitek Ex. 5 at DMI002617-19; Mitek Ex. 5 at ¶33), constructively reduced the invention to practice in February 1992 upon filing the application for the 446 Patent (Arthrex Ex. 8), and were diligent in reducing it to practice from before the filing date of the application for the 575 Patent (Mitek Ex. 4 at 284:4-287; Mitek Ex. 10; Mitek Ex. 11).

**Defendants Fact 61:**

Ethicon did not reduce to practice any product that included all the limitations of the asserted claims of the '446 patent before the filing date of the '446 because it never built a braid that was sterilized before the filing date, as shown above. "Sterilized" is a limitation of each asserted claim of the '446 patent. Ex. 8 at claim 1, 2, 8 , 9, 12.

**DePuy Mitek's Response to Defendants Fact 61:**

Denied. Arthrex's cited evidence only states that Dr. Steckel "believe[d]" that the braids were not sterilized at that point in the process, not that the braids were not sterilized (Arthrex Ex. 19 at 225:5-8), not that the braids were not sterile. Ethicon reduced to practice the claimed invention prior to the filing date of the 446 patent (Mitek Ex. 5 at ¶¶31-43). Ethicon constructively reduced the invention to practice upon filing the application for the 446 Patent (Arthrex Ex. 8).

**Defendants Fact 62:**

The '575 patent discloses every limitation of the asserted claims of the '446 patent. The '575 patent discloses a surgical suture. Ex. 15 at col. 2, l. 62; col. 3, ll. 2, 8, 15; col. 7, l. 26, 38, 43, 59; Ex. 10 at 212:25-213:5.

**DePuy Mitek's Response to Defendants Fact 62:**

Denied. Arthrex and Dr. Mukherjee have both admitted that the 575 Patent does not disclose every limitation of the asserted claims in prosecuting its 234 Patent (Ex. 3 to Mitek Ex. 5 at DMI041091; Mitek Ex. 6 at 182:23-183:17). The '575 patent does not disclose every limitation of the asserted claims of the '446 patent, and does not disclose a suture having all of the claim limitations (Mitek Ex. 5 at ¶9-30). Denied as the cite to column 2, line 62, and column 3, line 2 is to a sternum closure device (Mitek Ex. 5 at ¶16). Denied as the cite to column 3, lines 8 and 15 do not specify any construction. Denied as the cite to column 7, lines 26 and 38 is to a 100% Spectra product, and the cites to lines 43 and 59 are to a polyester braid with a spectra core (*id.* at ¶20). Denied as the citations to Ex. 10 do not say anything about the disclosure of Chesterfield. Also, Dr. Hermes has identified braided constructions that are not in direct intertwining contact (*id.* at ¶¶30, 59). Dr. Mukherjee agrees that there are braided constructions that are not in direct intertwining contact (Mitek Ex. 6 at 217:12-14; 218:23-219:3).

**Defendants Fact 63:**

The '575 patent discloses a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set. Ex. 15 at col. 2, l. 65 – col. 3, l. 2; Ex. 10 at 170:6-12; Ex. 15 at claim 1.

**DePuy Mitek's Response to Defendants Fact 63:**

Denied. Exhibit 15 at 2:65-3:2 does not disclose anything about different yarns. It refers to filaments. Claim 1 does not specify direct intertwining contact (Mitek Ex. 5 at ¶21). Dr. Mukherjee admits that braided construction includes all of one material in the sheath and all of one material in the core (Mitek Ex. 6 at 217:12-14; 218:23-219:3). Dr. Hermes has specified braided constructions which are not direct intertwining contact (Mitek Ex. 5 at ¶¶30, 59).

**Defendants Fact 64:**

FIG. 6 of the '575 patent discloses a spiroid braid with several yarns (items 26) that are braided in "direct intertwining contact." Ex. 10 at 201:24-202:5.

**DePuy Mitek's Response to Defendants Fact 64:**

Denied. The citation does not says that "several" yarns are braided in direct intertwining contact (Arthrex Ex. 10 at 201:24-202:5).

**Defendants Fact 65:**

The '575 patent discloses that one of the yarns braided together to form a suture is UHMWPE. Ex. 15 at col. 2, l. 31; Ex. 10 at 197:12-25

**DePuy Mitek's Response to Defendants Fact 65:**

Denied. Column 2, line 31 refers to a tape. The citation to Arthrex Ex. 10 refers to a "fiber," not a yarn, and does not refer to a "suture." Denied to the extent Arthrex has not identified what "braided together" means, and Arthrex has admitted that there is no braided structure that anticipates (Ex. 3 to Mitek Ex. 5 at DMI041091; Ex. 6 at 182:23-183:17; *see also* Mitek Ex. 5 at ¶¶9-30).

**Defendants Fact 66:**

The '575 patent discloses that one of the yarns braided together to form a suture is PET or nylon. Ex. 15 at claim 11; claim 12; Ex. 10 at 198:7-11, 14-18.

**DePuy Mitek's Response to Defendants Fact 66:**

Denied. Arthrex and Dr. Mukherjee have both admitted that the 575 Patent does not disclose PET or nylon disclosed with UHMWPE (Ex. 3 to Mitek Ex. 5 at DMI041091; Ex. 6 at 182:23-183:17). Denied as the 575 Patent does not disclose PET or nylon braided together with another material in direct intertwining contact (*id.*; Mitek Ex. 5 at ¶¶9-30). Also, Dr. Hermes has identified braided constructions that are not in direct intertwining contact (Mitek Ex. 5 at ¶¶30, 59). Denied as claims 11 and 12 of the 575 Patent do not disclose "braided together," braided in direct intertwining contact, as opposed to core sheath, by Arthrex's own admission (Ex. 3 to Mitek Ex. 5 at DMI041091; Ex. 6 at 182:23-183:17; *see also* Mitek Ex. 5 at ¶¶21).

**Defendants Fact 67:**

The '575 patent discloses that the suture is attached to a needle. Ex. 15 at col. 5, ll. 41-42.

**DePuy Mitek's Response to Defendants Fact 67:**

Denied as the fact has no antecedent for "the suture."

**Defendants Fact 68:**

The '575 patent discloses that UHMWPE can be constitute a volume fraction in the braided sheath and core from about 20-80%. Ex. 15 at col. 4, ll. 8-24; Fig.6.

**DePuy Mitek's Response to Defendants Fact 68:**

Denied as unintelligible with respect to "can be constitute." The '575 patent does not disclose that UHMWPE can constitute a volume fraction in the braided sheath and core from about 20-80% (Mitek Ex. 5 at ¶¶28-29).

**Defendants Fact 69:**

For these reasons, the '575 patent renders the asserted claims of the '446 patent invalid for anticipation.

**DePuy Mitek's Response to Defendants Fact 69:**

Denied. This "fact" improperly calls for a legal conclusion. The '575 patent does not render the asserted claims of the '446 patent invalid for anticipation (Mitek Ex. 5 at ¶¶9-43). The 575 patent is not prior art (*see* Mitek's Response to Fact #60).

**Mitek's Facts Submitted In Response To Arthrex's Summary Judgment Motion**

**Mitek Fact 128**

The 446 Patent claims all recite a surgical suture that consists essentially of a braid composed of a first and second set of continuous and discrete yarns, where

> each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and ***PE***.

(Arthrex Ex. 8 at 8:63-10:19).

**Mitek Fact 129**

Mitek's expert, Dr. Brookstein, also notes by declaration that ultra high molecular weight PE has many uses (Mitek Ex. 3 at ¶40).

**Mitek Fact 130**

Dr. David Brookstein provided two different and consistent analyses as to why FiberWire's ultra high molecular weight PE is equivalent to the claimed first-fiber forming materials (Mitek Ex. 3 at ¶¶16-34).

**Mitek Fact 131**

Dr. Brookstein opined that any differences between FiberWire's ultra high molecular weight PE and the claimed first fiber-forming materials are insubstantial because FiberWire's PE is consistent with the description of the preferred embodiments of the first fiber-forming materials in the 446 Patent (Mitek Ex. 3 at ¶17).

**Mitek Fact 132**

The 446 patent describes the preferred embodiments of the first fiber-forming materials as "lubricating yarns," "nonabsorbable polymers," and "fiber-forming materials" (*id.*).

**Mitek Fact 133**

Dr. Brookstein pointed out that FiberWire's PE is a lubricous, non absorbable, and fiber-forming material and concluded that differences between FiberWire's PE and the recited first fiber forming materials are therefore insubstantial (Mitek Ex. 3 at ¶¶16-17).

**Mitek Fact 134**

Dr. Mukherjee agrees that FiberWire's PE is lubricous and fiber-forming (Mitek Ex. 6 at 239:10-13; 296:4-6; 296:14-16).

**Mitek Fact 135**

FiberWire's PE is not bioabsorbable (Arthrex Ex. 14).

**Mitek Fact 136**

As Dr. Brookstein explained, the 446 patent describes embodiments in which PE is braided with PET, the PE is a lubricating yarn, and the PET improves strength of the heterogeneous braid (Mitek Ex. 3 at ¶20).

**Mitek Fact 137**

FiberWire is a braid of PE witih PET, the PE is lubricous, and the PET imparts strength (namely at least knot holding strength)[1] to the heterogeneous braid (*id.*).

**Mitek Fact 138**

Dr. Brookstein's opinion is supported by the testimony of Mr. Grafton, who was Arthrex's Vice President of Engineering and the alleged designer of FiberWire (Mitek Ex. 1 at 40:15-19; 44:5-7).

**Mitek Fact 139**

Mr. Grafton testified that, originally, Arthrex had considered a 100% ultra high molecular weight PE braid (Mitek Ex. 1 at 45-46).

**Mitek Fact 140**

But Mr. Grafton found this braid unacceptable because it was too lubricous and weak; it would not hold a knot (Mitek Ex. 3 at ¶18).

**Mitek Fact 141**

Arthrex discarded the idea of using PE until Mr. Grafton thought of braiding PET with the lubricous PE, so that the PET could impart knot holding strength to the braid and overcome the lubricous PE's disadvantages (*id.*).

**Mitek Fact 142**

Mr. Grafton's testimony about the development of FiberWire underscores that FiberWire is a braid of a lubricious first fiber-forming material with a second fiber-forming material to impart braid strength, like certain of the preferred embodiments in the 446 Patent (Arthrex Ex. 3 at 4:9-40).

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[1] Knot holding strength is a recognized suture strength property and is the force at which a knot fails by slipping, elongating to a certain extent, or breaking (Mitek Ex. 3 at ¶20).

**Mitek Fact 143**

Arthrex admitted in its U.S. Patent No. 6,716,234 that ultra high molecular weight PE "does not have acceptable knot tie down characteristics for use in surgical applications" (Mitek Ex. 3 at ¶20).

**Mitek Fact 144**

Mr. Grafton, a named inventor of the 234 patent, testified that knot tie down as that term is used in his patent is closely related to knot strength and is a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (*id.*).

**Mitek Fact 145**

According to Arthrex's 234 patent, this deficiency was overcome by braiding the lubricous PE with polyester or PET (Mitek Ex. 2 at 2:50-57).

**Mitek Fact 146**

Dr. Brookstein provided a function/way/result analysis in support of his opinion that the differences between ultra high molecular weight PE and the recited first fiber-forming materials are insubstantial (Mitek Ex. 3 at ¶¶21-34).

**Mitek Fact 147**

The function of the first fiber-forming materials is to contribute a property that is different than a yarn from the claimed second set of materials (Mitek Ex. 3 at ¶¶23-25).

**Mitek Fact 148**

The "way" the claimed first fiber-forming materials perform their function is to have "at least one yarn from the first set of yarns in direct intertwining contact with at least one yarn from the second set" (Mitek Ex. 3. at ¶26).

**Mitek Fact 149**

The "result" was "to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that, when they are braided, the yarns contribute to the properties of the overall heterogeneous braid" (Mitek Ex. 3 at ¶30).

**Mitek Fact 150**

FiberWire's braided PE performs these functions and obtains the same result in the same way as the recited first fiber-forming materials because it contributes lubricity and strength properties that are different than the second fiber-forming material, PET, and is braided in direct intertwining contact with at least one PET yarn (Mitek Ex. 3 at ¶¶23-34).

**Mitek Fact 151**

Dr. Mukerjee admitted that FiberWire's PE is lubricous (Mitek Ex. 6 at 239:10-13; 296:4-6; 296:14-16).

**Mitek Fact 152**

The 446 Patent states "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which makeup the yarns" (Arthrex Ex. 8 at 2:49-52).

**Mitek Fact 153**

The 446 Patent states "it is possible to tailor the physical . . . properties of the braid by varying the type and proportion of each of the dissimilar fiber forming used" (*id.* at 2:58-62).

**Mitek Fact 154**

The 446 Patent states in ***preferred embodiments*** the first fiber-forming materials can contribute other properties including "pliability," "compliance" and "surface lubricity" (*id.* at 4:11-13, emphasis added).

**Mitek Fact 155**

The sentence on which Arthrex relies (the sentence referenced in Mitek Fact 154) refers not only to pliability but also *compliance and surface lubricity* (*id.* at 4:12-13).

**Mitek Fact 156**

The properties in the sentence referenced in Mitek Fact 154 are for "preferred embodiments," not the invention as a whole (*id.* at 4:11).

**Mitek Fact 157**

The 446 Patent states "[i]f fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable" (*id.* at 2:22-25).

**Mitek Fact 158**

The 446 patent does not say that all braids made from all of the first fiber forming materials are all necessarily highly pliable or that the materials used to make the braids are "weak" (Mitek Ex. 5 at ¶¶49-51).

**Mitek Fact 159**

The first fiber-forming materials are never described in the 446 Patent as "weak" (Mitek Ex. 3. at ¶36).

**Mitek Fact 160**

PVDF and polypropylene (PP), which are among the materials listed in the group of first fiber-forming materials, are not "weak" (Mitek Ex. 3. at ¶¶36,37).

**Mitek Fact 161**

Like polyethylene, polypropylene is also available in an ultra high molecular weight form (Mitek Ex. 3 at Ex. 11).

**Mitek Fact 162**

Ultra high molecular weight PE is "weak" in at least two ways, knot holding properties and compression (Mitek Ex. 3 at ¶39) and some braids of ultra high molecular weight PE are weak (*see supra*).

**Mitek Fact 163**

FiberWire's PE is lubricous, while FiberWire's PET has a different lubricity (Mitek Ex. 3. at ¶¶17, 25).

**Mitek Fact 164**

FiberWire contributes to braid pliability because its lubricity allows the fibers and yarns to slide past each other when FiberWire bends (Mitek Ex. 3 at ¶40).

**Mitek Fact 165**

As the 446 Patent explains, material lubricity permits fiber-to-fiber mobility, so that when the braid is bent, the fibers can easily bend and slide past other fibers (Mitek Ex. 3. at ¶41).

**Mitek Fact 166**

Ultra high molecular weight PE has many purposes, it provides braid lubricity, surface properties, handleability properties, tensile strength, and detracts from knot holding strength (Mitek Ex. 3 at ¶40).

**Mitek Fact 167**

Dr. Burks is an experienced orthopedic surgeon (Mitek Ex. 9 at 11:24-17:17).

**Mitek Fact 168**

Dr. Burks allegedly conducted a blind test, including a knot tie down/handleability test, of uncoated and coated FiberWire for Arthrex and at his deposition (*id.* at 70:7-72:23; 91:20-99:6).

**Mitek Fact 169**

After examining the samples, Dr. Burks twice testified that the differences between the coated and uncoated samples were "subtle" (Mitek Ex., 9 at 87:7-13; 88:1-3; 96:18-19; 98:19-25); the coated and uncoated sutures were "pretty close" (*id.* at 88:1-3); and he "could not clearly feel a difference" between the two sutures (*id.* at 88:9-10).

**Mitek Fact 170**

Dr. Burks testified:

Q. How would you qualify the difference that you just observed, based on your test?

A. When you say "qualify" are you asking for like an amount?

Q. How would you characterize the difference between the sutures?

A. *Well the difference is, I think, subtle and there's no doubt in my mind that I could line up, you know, a hundred sutures and have error* where I would say, you know, I think this one is one way or the other and make a mistake. *So there's certainly not enough difference to clearly say that I know every time exactly how that feels.*

(*id.* at 97:15-98:3) (emphasis added).

**Mitek Fact 171**

Surgeons normally handle FiberWire in the surgical environment while wearing gloves (*id.* at 51:12-14).

**Mitek Fact 172**

When Dr. Burks conducted the blind test for Arthrex, he admitted that he may not have been able to tell a difference if he had not had his gloves off (*id.* at 73:9-14; *see also* 96:24-97:5).

**Mitek Fact 173**

Dr. Burks testified that

Q. Did using gloves in the tests in Exhibit 232 affect your ability to distinguish between suture A and suture B?

A. I think, clearly, using gloves makes the feel of the suture a little different. I guess I can't answer directly to say if it makes the difference but, yes, it probably makes a difference.

Q. What difference does it make?

A. You are covering your skin with the gloves, so, you know, as you feel suture, your absolute sensation of the suture probably changes some.

Q. Could you have reached the same conclusions you reached in Exhibit 232 if you solely used gloves in performing the tests?

A. I didn't do it that way, so I guess I can't answer that and say yes or no.

Q. Did not using gloves help you to distinguish between suture A and suture B?

A. Potentially, yes

(*id.*at 72:4-23).

**Mitek Fact 174**

FiberWire's coating is just silicone applied thinly to the braided suture as a surface lubricant as opposed to a monofilament-like coating which would materially affect fiber-to-fiber mobility (Mitek Ex. 3 at ¶47).

**Mitek Fact 175**

Dr. Brookstein confirmed that the silicone coating on FiberWire is present in small amounts and does not substantially penetrate the braid and create a monofilament like structure (*id.*).

**Mitek Fact 176**

Regardless of FiberWire's coating, FiberWire is still "two dissimilar yarns braided together to achieve improved handleability or pliability without significantly sacrificing its physical properties" (*id.*).

**Mitek Fact 177**

FiberWire has a very specific silicone coating that is applied to its surface (*id.*).

**Mitek Fact 178**

The 446 Patent specification defines coatings as optional or immaterial:

> *If desired*, the surface of the heterogeneous multifilament braid can be coated . . . to further improve handleability and knot tiedown performance of the braid.

(Arthrex Ex. 8 at 6:5-8) (emphasis added).

**Mitek Fact 179**

The 446 Patent specification draws a distinction between surface coatings, like FiberWire's, which do not significantly affect fiber-to-fiber mobility, and heavy coatings that significantly restrict fiber-to-fiber mobility and form monofilament-like structures (*id.* at 6:11-13; 8:50-61).

**Mitek Fact 180**

Dr. Brookstein's affidavit and testimony from Dr. Mukherjee, establishing that the coating on FiberWire does not materially affect its novel and basic characteristics, as they are defined by Mitek, are of record (Mitek Ex. 3 at ¶¶43-54; Mitek Ex. 6 at 562:20-25).

**Mitek Fact 181**

In 2001, Arthrex applied for a patent related to its FiberWire product (Mitek Ex. 2).

**Mitek Fact 182**

The Patent Office rejected Arthrex's claims over the 575 Patent (Mitek Ex. 5 at Ex. 3).

**Mitek Fact 183**

In response to that rejection, Arthrex argued that the 575 Patent "*does not disclose* an example of a braided sheath that includes a blend of both ultra high molecular weight polyethylene and polyester" (or PET) (*id.* at DMI041091) (emphasis added).

**Mitek Fact 184**

Arthrex and Dr. Mukehrjee admit that polyester includes PET (Arthrex Br. at 26).

**Mitek Fact 185**

Dr. Mukherjee testified that:

> Q. -- it says, the second sentence says, "As noted above, Chesterfield, et al., '575, does not disclose an example of a braided sheath that includes a blend of both -- of both ultra high molecular weight polyethylene and polyester."
>
> Do you see that?
>
> A. Yes.
>
> Q. Do you agree with that statement?
>
> A. Yes.

(Mitek Ex. 6 at 183:9-15).

**Mitek Fact 186**

The 575 Patent discloses that the spiroid braid of Figures 6 is comprised of a high molecular weight, high strength material and a bioabsorbable material (Mitek Ex. 5 at Ex. 2 at 4:11-13).

**Mitek Fact 187**

Even if the high molecular weight, high strength material in the spiroid braid of Figure 6 of the 575 Patent is understood to be ultra high molecular weight PE – one of the first fiber-

forming materials recited in the 446 Patent claims – there is no disclosure in the patent that the *second* material in the structure is one of the materials required by the claims, namely, PET, nylon or aramid (non-bioabsorbable materials) (Mitek Ex. 5 at 15-16).

**Mitek Fact 188**

The *claims* of the 575 Patent claims describe use of a sternum closure ribbon or tape, not a suture (Mitek Ex. 5 at ¶22).

**Mitek Fact 189**

Arthrex's counsel, Mr. Soffen, advised Arthrex that the 575 Patent claims do not describe the use of a suture (Mitek Ex. 12).

**Mitek Fact 190**

Claim 12 is directed to a method for repairing split portions of body tissue (Mitek Ex. 5 at ¶22).

**Mitek Fact 191**

The 575 Patent claims do not describe PE braided in direct intertwining contact with a polyester (Mitek Ex. 5 at ¶21-25).

**Mitek Fact 192**

Although claim 12 refers to polyester, it does not expressly specify how the polyester fibers are braided with the claimed first fibers of PE (*id.* at ¶21).

**Mitek Fact 193**

The 575 Patent claims merely recited a "braided" construction which could be a construction, such as a core-sheath arrangement as described in Figures 8 and 9, which is not a "direct intertwining contact" construction (*id.*).

**Mitek Fact 194**

The 446 Patent claims recite that the surgical suture is composed of "discrete yarns in a *sterilized*, braided construction." (Arthrex Ex. 8 at 8:65-66).

**Mitek Fact 195**

Claim 9 of the 446 Patent recites that "the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (*id.* at 9-11).

**Mitek Fact 196**

There is no disclosure in the 575 Patent of the recited volume fraction of claim 9 of the 446 Patent (Mitek Ex. 5 at ¶¶27-29).

**Mitek Fact 197**

Dr. Steckel testified, and his notebook confirms, that the invention of the 446 Patent was conceived of at least as early as June 1988, and that sutures were made and tested as least as early as February 1989 (Mitek Ex. 5 at ¶¶33-35).

**Mitek Fact 198**

Sterilization is a well known, commercialization step in suture development (Mitek Ex. 5 at ¶¶40-42).

**Mitek Fact 199**

Dr. Mukerjee testified that sterilization of suture materials was well-known at the time of the invention (Mitek Ex. 6 at 550:8- 551:1).

**Mitek Fact 200**

Dr. Steckel would only have sterilized if he intended to use the sutures in human surgery or to commercialize the invention (Mitek Ex. 5 at ¶¶41-42).

**Mitek Fact 201**

The 446 Patent inventors conceived of the invention at least as early as June 1988 (Mitek Ex. 5 at ¶33).

**Mitek Fact 202**

A memorandum from Mr. Goodwin, the attorney who prepared the application, and Dr. Steckel's testimony show that a draft application was sent to the inventors at least as early as January 1992 (Mitek Ex. 10; Mitek Ex. 4 at 284:4-17).

**Mitek Fact 203**

Also, Dr. Steckel's testimony and Mr. Goodwin's memorandum show that Mr. Goodwin finalized the application by trying to obtain comments from Dr. Steckel and contacting his supervisor when Dr. Steckel did not respond while he was in the process of moving from New Jersey to Ohio in January 1992 (Mitek Ex. 10 &11; Mitek Ex. 4 at 284:4-287:10).

**Mitek Fact 204**

Dr. Steckel's testimony further shows that he reviewed at least two draft applications, had email communications and discussions with counsel before the application for the 446 was filed, collected comments from the inventors, and finalized the application after completing his January move from New Jersey to Ohio in February 1992 (*id.* at 48:9-20; 264:19-271:23; 275:2-10; 276:4-281:25; 284:4-287:10).

**Mitek Fact 205**

According to Dr Mukherjee, "the function performed by the first fiber-forming materials is to add lubricity with the recognition that these materials will detract from the strength of the resulting suture" (Mitek Ex. 13).

**Mitek Fact 206**

The 446 Patent states that "highly pliable braids *can* be prepared," but that does not mean that *all braids* made from the materials are highly pliable because they can have different stiffness characteristics or be heat treated or processed in different ways to make the braids less pliable (Mitek Ex. 5 at ¶59).

**Mitek Fact 207**

Col. 2, line 24 states that "*in most cases,*" not all cases, these braids will be relatively weak (*id.*).

**Mitek Fact 208**

Col. 2, line 24-25 only refers to some *braids* as being weak, not the braided *materials* as being weak, as Arthrex incorrectly suggests (*id.*).

**Mitek Fact 209**

The 446 Patent says it would be *desirable* to form a braid with "enhanced pliability . . . without appreciably sacrificing physical properties," this is just one possible goal of the invention (Mitek Ex. 3 at ¶35; Mitek Ex. 5 at ¶50).

**Mitek Fact 210**

FiberWire's PE *does* detract from strength and *does* improve braid pliability (Mitek Ex. 3 at ¶¶18-20, 40).

**Mitek Fact 211**

Fiber *material* stiffness is a property dependent upon just the material properties and cross sectional shape of the specimen (Mitek Ex. 3 at ¶41).

**Mitek Fact 212**

*Braid* stiffness is dependent upon many parameters, including not only the stiffness of the braided materials, but also the manner in which they are braided, and, importantly, material lubricity (Mitek Ex. 3 at ¶41).

**Mitek Fact 213**

The 446 Patent inventors conceived of the invention at least as early as June 1988 (Mitek Ex. 5 at ¶33).

**Mitek Fact 214**

The 446 invention was constructively reduced to practice when the application for the 446 Patent was filed on February 19, 1992 (Arthrex Ex. 8).

Respectfully submitted,

Dated: September 1, 2006

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# EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

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Q. Let me back up to make sure this is clear. Knot strength versus knot tiedown. In your mind, are they the same thing or are they different?
A. I'm not sure I understand your question. Say that again.
Q. Sure. Knot strength --
A. Mmm-hmm (affirmative).
Q. -- which I think you testified that you understood to be tying a knot in a suture and pulling it on a tensile machine -- tensile tester machine to determine the strength at which the knot will break; right?
A. Yes.
Q. Okay. Then there's another term called knot tiedown, and I'm trying to understand whether, in your mind, you think that's the same as knot strength or do you use that term to mean something else?
A. They're closely related.
Q. And how are they related?
A. When you have a knot tiedown, you've tied a knot. The strength of the knot is going to affect the ability to hold -- to approximate the tissue in the tiedown area that you're talking about.
Q. If the knot had a good tiedown or a bad tiedown, what do you mean by that?

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A. Its ability to approximate the tissue and hold it in place through biomechanical forces.
Q. So that's related to knot strength, but it's not necessarily the same thing; is that the way you're using the term?
A. Yes.
Q. The way I heard you describe knot tiedown was you said the ability to approximate the tissue and hold it into place through biomechanical forces.
A. (Witness nods head affirmatively).
Q. When you say ability to approximate the tissue, what do you mean by that?
A. Shift tissue in the position that the surgeon would like for it to be on the bone.
Q. Shift tissue; did you say?
A. Yes.
Q. S-H-I-F-T?
A. Yes.
Q. So the knot's moving the tissue?
A. The suture is holding -- the suture loop with the knot in it, is holding the tissue in the position that the surgeon would like for it to be on bone.
Q. That's taking the place of the tissue? When you say approximate the tissue, how is it approximating tissue?

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A. It's -- The tissue is here. The location the surgeon wants it here. The suture loop as it is tied moves the tissue into position.
Q. Holds it there?
A. Yes.
Q. And what -- what biomechanical forces were you referring to?
A. Forces on the glenohumeral joint.
Q. In a knot strength test, it's the forces are being applied and generally in one direction; correct?
A. Yes.
Q. The biomechanical force that you are referring to in this knot tiedown, the forces are coming from different directions; right?
A. Yes.
Q. Okay. When you are referring to knot tiedown then, you're referring to -- you're referring to it in a sense as a strength?
A. Are you finished? Is that the question?
Q. Right.
A. I don't believe -- Say it again then.
Q. Sure. Knot tiedown, the way you're referring to it, it's a strength then? It's kind of like -- because knot strength would be measured in p.s.i.
A. I said that's one of the attributes of it.

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That's not the total attribute of it. I mean it's to approximate tissue into position is knot tiedown.
Q. Well, what else would be included?
A. I just told you. Approximate tissue, strength.
Q. So the strength would -- I understand the --
A. The size of the knot bundle. You know, there's --
Q. Size of the knot bundle?
A. Yes.
Q. What do you mean by that?
A. How large the knot is once it has been tied and cut.
Q. So knot tiedown includes the size of the knot bundle?
A. Yes. You know, the knot tiedown -- I want to say this -- that's not a term that we specifically use, so it's a little bit foreign. I mean I don't -- I've never had a surgeon ask me about knot tiedown.
Q. Okay.
A. So I didn't -- your -- I'm not sure where you're going with this, but there's -- we did knot testing and we did straight pull testing of the suture so that your knot tiedown, I'm -- I'm not real sure what you're asking for there. I --
Q. Well --

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Q. And do you know how many yarns were used in the polyester?
A. No.
Q. No?
A. No.
Q. Okay. How about the Tevdek suture? Was that made on a carrier braider?
A. Yes.
Q. Do you know how many yarns were used in the Tevdek suture?
A. No.
Q. Was the polyester suture from Pearsalls, was that, after it was braided, was it heated up and melted together?
A. I don't know.
Q. Okay. How about the Tevdek suture? Was that heated up --
A. I don't know.
Q. -- and melted together?
A. Do not know.
Q. After -- Let me back up. Any problems with the Tevdek suture?
A. Yes.
Q. What were the problems with the Tevdek suture?
A. Tensile strength was low.

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Q. Any others?
A. That's enough.
Q. Okay. Were there --
A. That will kill the product.
Q. Okay.
A. Others were -- the others were insignificant, if there were some. That killed the product.
Q. That killed the product?
A. Yes.
Q. Okay. How about the knot strength of the Tevdek suture? Was that low?
A. If your tensile strength is low, sir, we're talking about straight pull, knot pull, that would cover both categories.
Q. Okay. So the knot strength of the Tevdek suture was low, too?
A. Yes.
Q. So that was part of the reason why the Tevdek suture was killed? Is that the word?
A. Yes.
Q. How about the knot tiedown Tevdek suture? How was that?
A. I have already been through that with you. We tested for tensile strength in knot and straight pull; okay? So to answer your question, if those two were low,

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then -- then you would expect the knot tiedown, the term you have been using, to also be low.
Q. If the knot strength and tensile strength are low, you expect the knot tiedown to be low?
A. Yes.
Q. If the knot tiedown's low, do you expect the knot strength to be low?
A. Don't know.
Q. Is it -- Were these complaints from surgeons about the Tevdek suture, about the strength?
A. That's correct.
Q. And is that when the development of FiberWire began?
A. Yes.
Q. Let me back up. When you started with Arthrex, what was your position?
A. Vice President of Engineering.
Q. And how long did you hold that position?
A. Total time I was there.
Q. And when you started at Arthrex, how many people reported to you?
A. Zero.
Q. And when you left Arthrex, how many people reported to you?
A. Approximately 15. I'm not sure.

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Q. So after Arthrex, have you been employed?
A. No.
Q. And you left Arthrex when?
A. January of 2005.
Q. I will show you DePuy Mitek Exhibit 129. This is Defendant Pearsalls, Limited's Initial Disclosures in this case. Under the first section, A, it says, "Individuals likely to have discoverable information that Pearsalls may use to support its claims or defenses." And the first person listed is Mr. Reinhold Schmieding. Do you see that?
A. Yes.
Q. Then if you turn to the second page, the second person listed is you. Do you see that?
A. Yes.
Q. It says that you are familiar with the development, marketing and sales of Arthrex's FiberWire, surgical suture products, and decisions about offering those products into the market." Do you see that?
A. Yes, I do.
Q. Do you agree with that?
A. Yes.
Q. It says, "Mr. Grafton is familiar with the state-of-the-art for surgical suture products." Do you see that?

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A. What's the date on this?
Q. The date on this is -- the last page is dated November 4th, 2005.
A. Okay. I want to quantify this then, because you're talking about a time period after I worked for the company, so when you -- when it says in here that I'm familiar with these products, it would be at the time I had left the company. And this is -- this was written after I left the company. So I can't totally say that I am familiar with those products under that.
Q. So you would agree that you were familiar with the state-of-the-art for surgical suture products as of the date you left Arthrex?
A. Define state-of-the-art, sir.
Q. State-of-the-art? Well, the general -- You don't have an understanding of what that means?
A. I want to understand what you mean in the context of this state-of-the-art.
Q. Okay.
A. I mean there's -- there's -- there's --
Q. This is from Pearsalls, so I can't tell you exactly what they mean, so ... Let me back up. When you were --
A. I was -- I was familiar with the competitive products on the market and what we offered and how they

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compared to the competitive products.
Q. Okay. And that was as of the date you left Arthrex?
A. Yes.
Q. Okay. And how long were you familiar with Arthrex's suture products and the competitive suture products that are in the marketplace?
A. When we started marketing the product, the sutures, until the time I left.
Q. Okay. So sometime when Arthrex began selling the suture from the supplier from New Mexico?
A. Yes.
Q. Okay. When Arthrex shifted from the Pearsalls suture to the Tevdek suture, was there any consideration to -- or for Arthrex designing its own suture?
A. No.
Q. Why not?
A. Because we could find a suture OEM that was available already. Why manufacture the suture when there's a readily available source?
Q. Now you said you tested for the Tevdek suture before it was selected; right?
A. Of course.
Q. And then it came back after it was selected, the response from surgeons was that it had low knot strength

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and tensile strength; right?
A. Yes.
Q. Didn't that come up in your testing?
A. I don't recall.
Q. What was your involvement in the development of FiberWire?
A. It was my idea.
Q. When you say it was your idea, what do you mean by that?
A. I'll give you -- Would you like the story on how FiberWire came about?
Q. Sure.
A. We were having issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon.
Q. Ethibond?
A. Ethibond. This was numerous complaints from friendly surgeons, not -- not a massive amount of complaints, but it was determined that the tensile strength of the suture was not as good as the Ethicon Ethibond suture.
Q. When you say friendly, do you mean friendly to Arthrex?
A. Yes. And I had gotten a phone call from a Dr.

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Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said it kind of jokingly. He said, "And I didn't even work out the day before."
And so he was tying to be nice about it, but bottom line was your suture sucks. Okay?
And so -- you know -- we're in a position where we need to find a suture that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.
One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra-high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.
I had Pearsalls, mainly through Brian, as being the manufacturing person --
Q. Brian Hallett?

A. That's correct -- make some Size 2 braided material, send to me, and at the -- coincidentally, at the same time, I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who is a R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up.

We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.

So at that point in time, it looked like we would not be able to use an alternative material of ultra-high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.

I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra-high molecular weight polyethylene to enhance the or reduce the knot slippage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra-high molecular weight PE, of adding the PET, and his -- I'll never forget the e-mail. He thought that was a killer idea.

And so I had asked then at that time for Brian



Hallett to make me samples up of using those two materials and -- and send to me. And we tested the materials, and now we had a product that had superior tensile strength and greater knot strength than any competitive product out on the market.

Q. Okay. If I could just back up to a couple of points that you mentioned to make sure I understand what happened here. The -- You said the idea began -- or I'm sorry. Back up. You said when this idea came up, you had already been to Pearsalls several times?

A. Mmm-hmm (affirmative).

Q. And you were familiar with --

A. Yes.

Q. And when this idea came up, you were familiar with how sutures were manufactured?

A. Yes.

Q. Okay. And what did you mean by that?

A. One of the products -- projects that I worked on was a bioabsorbable suture similar to what Ethicon sells as Panacryl, and the difference being this was 100 percent PLLA material. The -- so we worked on this for about a year -- I don't know the exact time -- with many trips over to Pearsalls to change the construct of the yarn to enhance the tensile properties of the material. And so at that time, I became familiar with how a suture is



processed to make a braid.

Q. Okay. And how many times were you over in England?

A. I told you already. Three to five.

Q. Three to five.

A. Approximate.

Q. Is that total lifetime?

A. That's an approximate number total lifetime, yes.

Q. Have you been to other manufacturing facilities for sutures?

A. Jenzyme Tevdek.

Q. And how many times have you been there?

A. Once, I believe.

Q. And when you were at Jenzyme Tevdek, did you see the manufacturing processes for Tevdek?

A. It was a dog and pony quick courtesy through the facility.

Q. So when you came up with the idea for using ultra-high molecular weight polyethylene in a suture, did you -- you say you are familiar with how sutures are made?

A. I'm also a fisherman. There's -- you know -- fishing line is -- uses ultra-high molecular weight polyethylene as a material that's used for sport fishing, very high strength.

Pearsalls made fishing line. And so they had



this material already available as a fishing line. So it was an easy conversion -- you know -- conclusion, conversion to say what if this is used as a suture material, because ultra-high molecular weight polyethylene is a totally inert material.

Q. When you saw that Pearsalls had been using ultra-high molecular weight polyethylene in fishing line --

A. Yes.

Q. -- do you know how it was being used in fishing line, what the construction was?

A. No.

Q. Was it a braided construction? Was it --

A. I can't tell you for sure, sir.

Q. You don't know?

A. I wasn't interested in buying fishing line, so I didn't look at the details of it.

Q. So you had -- Sitting here today, you can't tell me anything at all about how the fishing line that Pearsalls was making with ultra-high molecular weight polyethylene was constructed?

A. It went through their manufacturing processes in their company, but specifically how it was made, the constructs, I have no idea or the size.

Q. In other words, you have no idea if it was all

50

1 ultra-high molecular weight polyethylene or if it was
2 braided or --
3 A. It's been too long ago. I can't tell you that.
4 Q. And your idea was to use the ultra-high molecular
5 weight polyethylene as a suture?
6 A. Yes.
7 Q. Okay. And you had Mr. Hallett make a Size 2, I
8 think you said?
9 A. Yes.
10 Q. Okay. Can you describe the construction of that
11 first --
12 A. I don't remember now. It's been too long.
13 Q. Was it all ultra -- ultra-high molecular weight
14 polyethylene?
15 A. Initially, yes, as a test prototype material.
16 Q. Was it braided?
17 A. Yes.
18 Q. Was it an eight-carrier or a sixteen-carrier?
19 A. I don't remember.
20 Q. You said it was a Size 2 though?
21 A. Yes.
22 Q. So it was a Size 2 ultra-high molecular weight
23 polyethylene braided suture that did not have PET?
24 A. For the initial prototype material, that's
25 correct.

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1 Q. Okay. And it didn't have nylon or any other
2 material braided with it?
3 A. No.
4 Q. So the initial prototype was a ultra-high
5 molecular weight polyethylene braided suture prototype, if
6 you will?
7 A. Yes. Size 2.
8 Q. Size 2. And was the initial prototype, was it
9 coated?
10 A. I don't remember.
11 Q. Okay. Do you know if the initial prototype went
12 through any other manufacturing process like stretching or
13 heating, twisting?
14 A. I don't recall.
15 Q. Was the initial prototype 100 percent ultra-high
16 molecular weight polyethylene?
17 A. For the fourth time, yes.
18 Q. Okay. And you tested the initial prototype that
19 was 100 percent ultra-high molecular weight polyethylene
20 with Dr. Burkhart and Dr. Chen?
21 A. Dr. Casey Chen, correct.
22 Q. Okay. And the test that you conducted with Dr.
23 Burkhart and Dr. Chen on the ultra-high molecular weight
24 polyethylene was a knot strength test?
25 A. Knot security.

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1 Q. Knot security test?
2 A. Yes.
3 Q. Was that the test we drew in Exhibit Number 421?
4 A. That's correct.
5 Q. Okay. And you said the strength was excellent, I
6 believe, of the initial prototype, but the knot slippage
7 was poor; is that right?
8 A. Yes.
9 Q. Okay. When you say the slippage was poor of the
10 initial prototype, what do you mean?
11 A. Less than the tensile strength capability of the
12 existing Arthrex product.
13 Q. So the knot slippage was less than the Tevdek
14 suture?
15 A. Yes.
16 Q. And it was -- knot slippage was such that it was
17 determined that the 100 percent ultra-high molecular
18 weight polyethylene suture prototype wasn't suitable to be
19 developed?
20 A. That's correct. Yes.
21 Q. Okay. Ultra-high molecular weight polyethylene,
22 you said the knot slippage was poor?
23 A. (Witness nods head affirmatively).
24 Q. Ultra-high molecular weight polyethylene, is that
25 a lubricious material?

53

1 A. Yes.
2 Q. And was the knot slippage of this ultra-high
3 molecular weight polyethylene poor security because of the
4 lubricity of polyethylene?
5 A. Yes.
6 Q. Yes?
7 A. Yes.
8 Q. So then you came up with the idea to braid PET
9 with the ultra-high molecular weight polyethylene to
10 reduce the knot slippage?
11 A. Yes.
12 Q. And when you say knot slippage, we're referring
13 to this knot security test?
14 A. Yes.
15 Q. So are we using the terms knot slippage and knot
16 security interchangeably here?
17 A. You are, yes.
18 Q. In your testimony?
19 A. Yes.
20 Q. So the knot security of the 100 percent
21 ultra-high molecular weight polyethylene was poor, the
22 prototype; right?
23 A. Yes.
24 Q. And your idea was to add the PET and to improve
25 the knot security?

done on any product. Obviously, there needed to be a check -- there's a checklist -- okay -- so I'm going by memory, that it needed to be looked at from a patent standpoint to see if there was any infringing as well as whether the product was compatible, along with the GNP items that are required for the product.

Q. Okay. Those things you are describing to me, those were all kind of commercial considerations. My question is a little different. Maybe my question wasn't clear. My question was more along the lines of once you had the prototype of the ultra-high molecular weight polyethylene and PET braided together and you tested it and you believed that it would work as a suture, I understand there's things you needed to do to make it a commercial product.

Was there anything else you needed to do in your mind to clarify whether it needed to -- whether it could work as a suture?

A. We needed to have a surgeon look at it that would actually be tying knots with it to get their understanding of -- of how they felt about the suture.

Q. Okay. Anything else though?

A. Not that I recall.

Q. Okay.

MR. SOFFEN: Is it time for a break? In a few



minutes?

MR. BONELLA: Yeah. Just give me five. Let me just finish this line of questions.

Q. Was the initial prototype that was ultra-high molecular weight polyethylene, was that sterile?

A. I don't remember.

Q. How about the prototype that was PET and ultra-high molecular weight polyethylene braided together? Was that sterile?

A. I don't remember.

Q. Would it have to have been sterile? Would the prototypes have to have been sterile?

A. Not to test on the tensile test machine.

Q. Why not?

A. Because it's not going into a human. You don't -- The bioburden levels at that point is not a factor that was wrong.

Q. Was sterilization another process at that time? Was that something you really didn't have to account for?

A. Say the question again.

Q. I'm just making sure that what you're saying is that sterilization is just to -- was just to -- it's really for biocompatibility? It's not to change the properties of the material; is that right?

MR. SOFFEN: Objection; vague.



A. I don't know. I don't know. That's really a weird question.

Q. I understand you are saying they weren't sterile.

A. No. I didn't say -- I said I don't recall, sir.

Q. You don't recall?

A. Yes.

Q. Okay. And my question was would they have had to have been, and you said, I think, no because they were testing them for mechanical properties.

A. Yes.

Q. Okay. Did you -- Would the sutures have had to have been sterile when you tested them for mechanical properties?

A. I already answered that.

MR. SOFFEN: Objection; asked and answered.

A. I said no. It didn't have to be to be tested on a tensile test machine.

Q. And why is that?

A. I already answered that also. It's not being used for human or animal use, so the biocompatibility issues of the suture at that time were not looked at. The mechanical features of the suture were all that were looked at at that portion of the prototype stage.

Q. Did sterilization have a big effect on the mechanical properties of the suture, the tensile?



MR. SOFFEN: Objection.

A. I -- I can't answer that question.

Q. You don't know?

A. No.

Q. But when you made the decision to go forward with this, you can't remember whether they were sterile or not?

A. You asked me -- You're -- you're kind of putting a couple of things together, so that's why you're --

Q. Okay. Maybe I'm getting confused.

A. You asked me if the prototypes were sterile, and I said no.

Q. Okay.

A. The decision to go forward with the product, obviously, there has to be sterilization done before the product can be marketed.

Q. Absolutely. And are you saying that the decision to go forward with it was made before you tested a sterile product?

A. I can't say that.

Q. Do you recall testing a sterile product before the decision was decided to make -- decided to go forward with the PET and the --

A. I don't remember.

Q. -- ultra-high molecular weight polyethylene?

A. I don't -- It depends on what point in time you

# EXHIBIT 2

US006716234B2

(12) **United States Patent**
**Grafton et al.**

(10) **Patent No.: US 6,716,234 B2**
(45) **Date of Patent: Apr. 6, 2004**

(54) **HIGH STRENGTH SUTURE MATERIAL**

(75) Inventors: **R. Donald Grafton**, Naples, FL (US); **D. Lawson Lyon**, Exeter (GB); **Brian Hallet**, Taunton (GB)

(73) Assignee: **Arthrex, Inc.**, Naples, FL (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

(21) Appl. No.: **09/950,598**

(22) Filed: **Sep. 13, 2001**

(65) **Prior Publication Data**

US 2003/0050666 A1 Mar. 13, 2003

(51) **Int. Cl.**[7] ..... **A61L 17/04**
(52) **U.S. Cl.** ..... **606/228**
(58) **Field of Search** ..... 606/228

(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | | | |
|---|---|---|---|---|---|
| 3,942,532 | A | | 3/1976 | Hunter et al. | |
| 4,047,533 | A | * | 9/1977 | Perciaccante et al. | 606/230 |
| 4,344,908 | A | | 8/1982 | Smith et al. | 264/203 |
| 4,411,854 | A | | 10/1983 | Maurer et al. | 264/205 |
| 4,422,993 | A | | 12/1983 | Smith et al. | 264/210.8 |
| 4,430,383 | A | | 2/1984 | Smith et al. | 428/364 |
| 4,436,689 | A | | 3/1984 | Smith et al. | 264/204 |
| 4,668,717 | A | | 5/1987 | Lemstra et al. | 523/322 |
| 5,019,093 | A | * | 5/1991 | Kaplan et al. | 606/228 |
| 5,067,538 | A | | 11/1991 | Nelson et al. | 152/451 |
| 5,234,764 | A | | 8/1993 | Nelson et al. | 428/364 |
| 5,261,886 | A | * | 11/1993 | Chesterfield et al. | 606/228 |
| 5,318,575 | A | | 6/1994 | Chesterfield et al. | 606/151 |
| 5,383,925 | A | * | 1/1995 | Schmitt | 623/1.53 |
| 5,403,659 | A | | 4/1995 | Nelson et al. | 428/364 |
| 5,540,703 | A | | 7/1996 | Barker, Jr. et al. | |
| 5,630,976 | A | | 5/1997 | Nelson et al. | 264/210.8 |
| 5,720,765 | A | * | 2/1998 | Thal | 606/232 |
| 6,045,571 | A | * | 4/2000 | Hill et al. | 606/228 |
| 6,063,105 | A | * | 5/2000 | Totakura | 606/228 |

FOREIGN PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| EP | 0561108 | A2 | 9/1993 |

OTHER PUBLICATIONS

"SecureStrand™ Cable System," Surgical Dynamics, Inc. 1999.

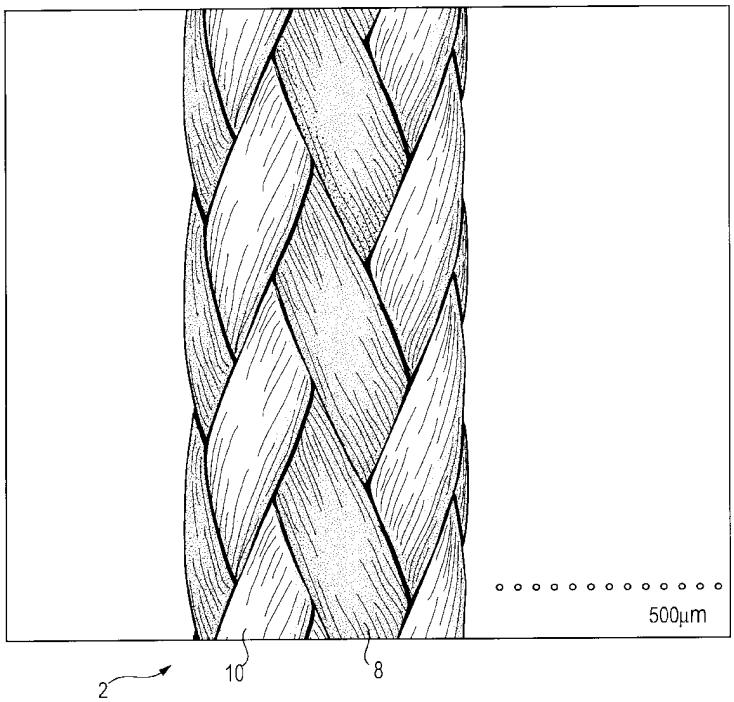
* cited by examiner

*Primary Examiner*—David O. Reip
(74) *Attorney, Agent, or Firm*—Dickstein Shapiro Morin & Oshinsky, LLP

(57) **ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

**9 Claims, 2 Drawing Sheets**



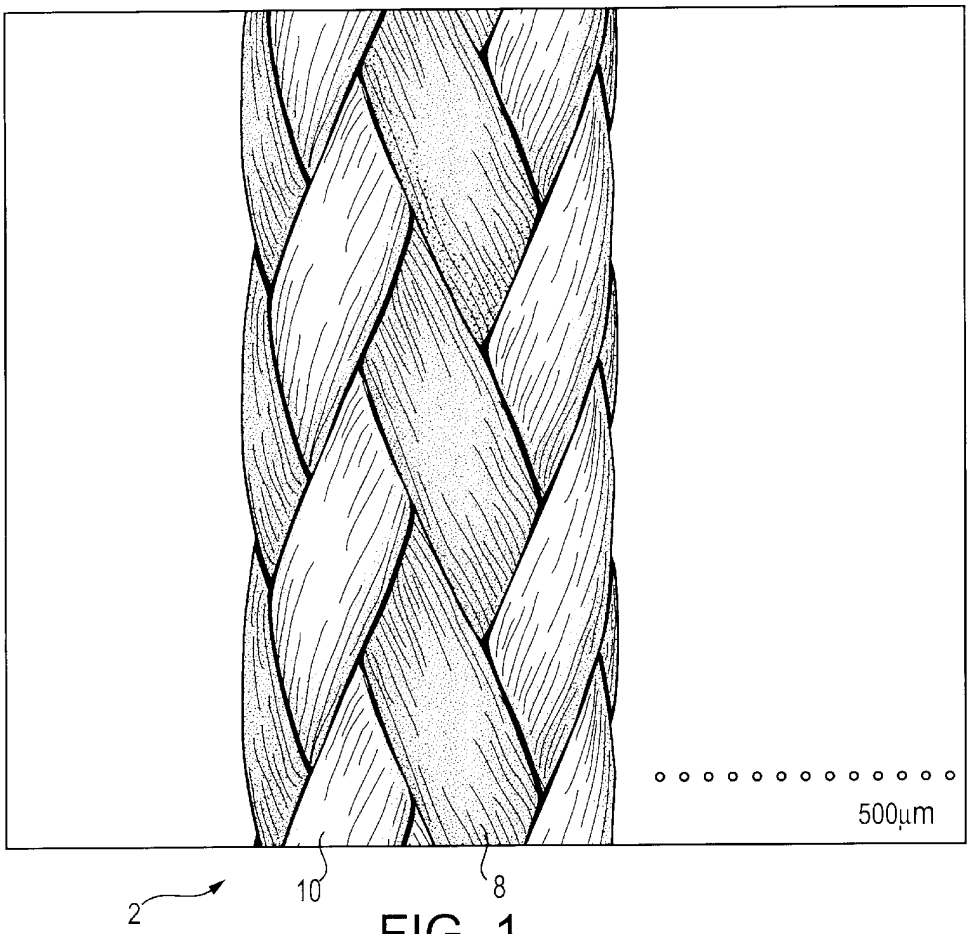



FIG. 1

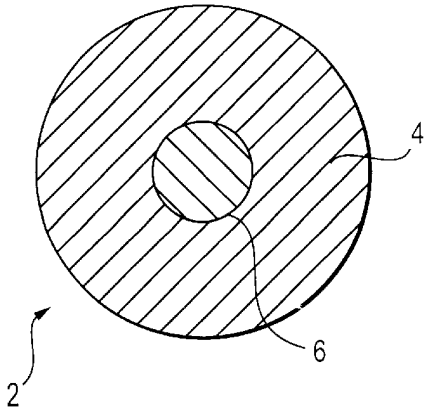



FIG. 2

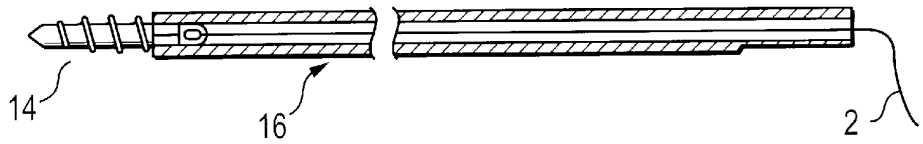



FIG. 3

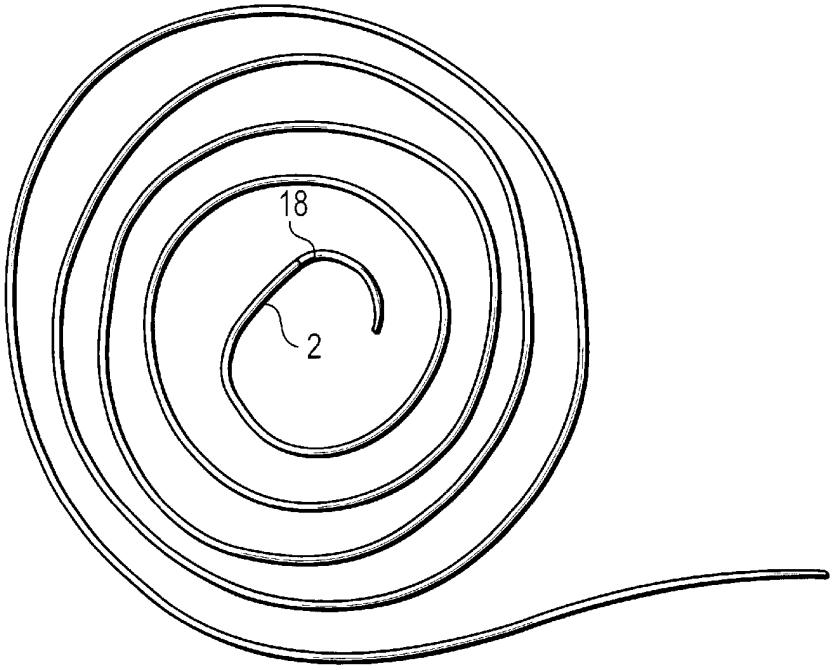



FIG. 4A

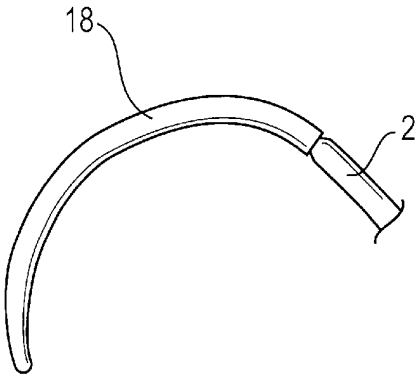



FIG. 4B

# HIGH STRENGTH SUTURE MATERIAL

## BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

## SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, archilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. **1** is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. **2** is a schematic cross section of a length of suture according to the present invention.

FIG. **3** is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. **4**A and **4**B show the suture of the present invention attached to a half round, tapered needle.



## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, a scanning electron micrograph of a length of suture **2** according to the present invention is shown. Suture **2** is made up of a cover **4** and a core **6** surrounded by the cover. See FIG. **2**. Strands of ultrahigh molecular weight polyethylene (UHMWPE) **8**, sold under the tradename Dyneema or Spectra, and strands of polyester **10** are braided together to form the cover **4**. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

### EXAMPLE 1

USP Size 5 (EP size 7)

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers×190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers×220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers×440 d'tex=1320 d'tex) is 28.69% of the suture.

### EXAMPLE 2

USP Size 2

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

In one method of using the suture of the present invention, the suture **2** is attached to a suture anchor **14** as shown in FIG. **3** (prepackaged sterile with an inserter **16**), or is attached to a half round, tapered needle **18** as shown in FIGS. **4**A and **4**B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

**1**. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

**2**. The suture filament of claim **1**, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

**3**. The suture filament of claim **1**, wherein the polyester comprises about 40% of the braided fibers.

**4**. The suture filament of claim **1**, wherein the core comprises a bout 30% of the filament.



**5**. The suture filament of claim **1**, wherein the cover comprises about 70% of the filament.

**6**. The suture filament of claim **1**, further comprising a coating disposed on the cover.

**7**. The suture filament of claim **1**, wherein the polyester is non-absorbable.

**8**. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

**9**. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

* * * * *

# EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

| | | |
|---|---|---|
| **DePuy Mitek, Inc.**<br>**a Massachusetts Corporation**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**Arthrex, Inc.**<br>**a Delaware Corporation and**<br><br>**Pearsalls Ltd.,**<br>**a Private Limited Company**<br>**of the United Kingdom,**<br><br>**Defendants.** | ) | **Civil No. 04-12457 PBS** |

**Declaration of Dr. David Brookstein In Support of DePuy Mitek's**
**Claim Interpretation of the Hunter Patent and Summary Judgment of Infringement**

## I. Background Information

### A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and conducted research in

the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

**B. Work Experience**

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

**C. Education**

6. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

7. I have a Master of Science in Textile Technology from M.I.T., 1973.

8. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

9. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

10. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based,

resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

11. My publications and patents for which I am an inventor are listed in my curriculum vitae (Ex. 1).

12. I have been asked to prepare this declaration based on my prior reports, deposition testimony, and Arthrex's motion for summary judgment. This declaration is basically my prior opinions reformatted to address the issues that I have been asked to address.[1]

**II. Legal Framework of My Opinions**

13. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

14. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

15. Infringement is "literal" when each claim limitation is literally present in a device. I understand that even if a device does not literally have each claim limitation, there is still

[1] For purposes of this declaration, I use the term FiberWire to refer to Arthrex's FiberWire and TigerWire's products except where noted.

infringement if the device has an equivalent of the claimed limitation that is not literally present. I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused device "performs substantially the same function in substantially the same way to obtain the same result" ("function/way/result test") as the claimed element.

## III. If "General Purpose PE" Is Deemed Not To Literally Include FiberWire's Braided PE, Then FiberWire Infringes Under the Doctrine of Equivalents

### A. The Differences Between FiberWire's PE and the Claimed First Fiber-Forming Materials Are Insubstantial

16. If "PE" as claimed in the 446 Patent is construed to mean "general purpose PE" (Arthrex Brf. on Claim Construction at 10, hereinafter "Arthrex Br."), and it is found that FiberWire's braided PE is not literally "general purpose PE," then it is my opinion that there is infringement under the doctrine of equivalents because the differences between FiberWire's braided PE and the first fiber-forming materials are insubstantial.

17. In a preferred embodiment, the 446 Patent describes the first fiber-forming materials as acting "as lubricating yarns" (Ex. 2 at 4:11-12). PE, including UHMWPE, is a lubricious material (Ex. 3 at 52:24-53:1). Further, the 446 Patent explains that the first set of yarns may be "non-absorbable polymers" (Ex. 2 at 4:10-11). UHMWPE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber-forming materials (Ex. 2 at 2:45-46). UHMWPE is a fiber-forming material. Therefore, the 446 Patent's description of the first-fiber forming materials is consistent with UHMWPE. Moreover, UHMWPE is consistent with the more general description of the invention, as set forth in column 2, lines 40-63, column 3, lines, 21-28, 40-65, and column 6, lines 50-56.

18. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. 3 at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (*id*. at 51:15-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (*id*. at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (*id*. at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e*., the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (*id*. at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. This just like the 446 Patent because the 446 Patent describes embodiments in which the first fiber-forming materials are lubricous and the second fiber-forming materials impart strength. Accordingly, FiberWire's braid is not, as Arthrex has suggested, the opposite of what is described in the 446 Patent.

19. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. 4 at 1:19-21; Ex. 3 at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. 3 at 26:24-27:6). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength. According to Arthrex's 234 patent, this problem was overcome by braiding UHMWPE with

polyester (Ex. 4 at 2:50-57). As the 234 patent explains, braiding polyester with UHMWPE improves knot tie down characteristics or the "ability to approximate the tissue and hold it in place through biomechanical forces" (Ex. 3 at 26:24-27:10). Thus, the 234 patent teaches that polyester, which includes materials such as PET, imparts knot tie down or knot holding strength to a braid of UHMWPE and polyester. Thus, Arthrex's 234 Patent further shows that the differences are insubstantial because UHMWPE is described as a lubricous yarn that with bad knot properties, and similarly embodiments of the first fiber-forming materials are described as lubricous.

20. I understand that Arthrex has asserted that the differences between the first fiber-forming materials (if PE does not include UHMWPE) and UHMWPE are substantial because the purpose of UHMWPE in FiberWire is alleged to be to provide strength (Arthrex Br. at 11). I disagree with this statement because the 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. 2 at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire's UHMW PE is lubricous (Ex. 3 at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, "to provide improved strength to the heterogeneous braid" (Ex. 2 at 4:33-36). FiberWire is consistent with this description; FiberWire's PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. 3 at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,[2] of

[2] I use the term "knot pull strength" to refer to the force at which a suture having a knot tied in it fails when tested in a tension test. I use the term "knot holding strength" to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Exs. 26 and 27. Knot holding strength is an indication

the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot. Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

### B. The Differences Between the Claimed First Fiber-Forming Materials And FiberWire's PE Are Insubstantial Based On the Function/Way/Result Analysis

21. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial under the function/way/result analysis.

22. I have used the "function/way/result" test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

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of knot security. The 446 Patent describes another exemplary knot security test (Ex. 2 at 6:36-44).

23. In my opinion, the "function" of the first fiber-forming material is the same as the function of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

| **Claims 1, 2, 8, 9, and 12 Limitation** | **Function of Limitation Under the Doctrine of Equivalents** | **Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products** |
|---|---|---|
| a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and | The function of the first set of yarns is to contribute a property that is different than a yarn from the second set. | UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET. |

24. My opinion regarding the "function" of the first fiber-forming material is supported by the '446 Patent. The '446 Patent explains that the first fiber forming material is "dissimilar" to the second fiber and the braid of dissimilar yarns provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. 2 at 2:50-52; 3:43-48). Further, the '446 Patent explains that it is possible to "tailor the physical" properties by "varying the type and proportion of each of the dissimilar fiber forming materials used" (*id*. at 2:58-61). Also, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (*id*. at 8:19-21).

25. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid.

Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHWMPE and the flexibility of PET (Ex. 5 at 306:17-307:14; Ex. 6; *see also* Ex. 5 at 307:15-308:14; Ex. 7). Further, as I explained in my rebuttal report with respect to Mr. Grafton's work and Arthrex's 234 Patent, FiberWire's PE also provides lubricity and other surface properties that are different than PET, and PET when braided with PE in FiberWire increases the knot holding strength.

26. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

| **Claims 1, 2, 8, 9, and 12 Limitation** | **"Way" of Limitation Under the Doctrine of Equivalents** | **Way UHMWPE performs its Function in FiberWire™ and TigerWire™** |
|---|---|---|
| a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and | The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set. | At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Ex. 8 at 99-107). |

27. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct intertwining contact" with a yarn from the second set (Ex. 2 at 2:40-44; *see also* 3:21-28; 3:40-45). The '446 Patent further explains that the heterogeneous braid properties are due to the "mechanical interlocking or weaving of the individual yarns" (*id*. at 2:56-58; 3:43-48). Also, during the

prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct "intertwining" contact of dissimilar yarns (Ex. 9 at 2, emphasis original).

28. Further, the '446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Ex. 2 at 4:9-59). The '446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (*id*. at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials, so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these "preferred embodiments," and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

29. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products have the same "way" as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex's FiberWire™ and TigerWire™ products is braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex's and Pearsalls' testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Ex. 8 at p. 99-107).

30. In my opinion, the "result" of the first forming material is the same as the result of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

| **Claims 1, 2, 8, 9, and 12 Limitation** | **"Result" of Limitation Under the Doctrine of Equivalents** | **Result of UHMWPE in FiberWire™** |
|---|---|---|
| a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and | The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid. | The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid. |

31. My opinion regarding the "result" of the first-forming material is supported by the '446 Patent. For example, the '446 Patent explains that the "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials" (Ex. 2 at 2:49-52). Further, the '446 Patent states that the "types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties." (*id*. at 6:52-56).

32. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. In FiberWire™, when the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET. Also, as I explained in my rebuttal report and through my declaration with reference to Arthrex's 234 Patent, Mr.

Graftons' work, and the development of FiberWire, UHMWPE adds lubricity, pliability, and surface properties that are different than PET.

33. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

> Q What did you understand Mr. Grafton to mean when he said:
> "Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".
> What did you understand that to mean?
> A Yes, that he wanted a braid which was more -- not so stiff.
> Q As the 100% ultra high molecular weight polyethylene?
> A Yes. (Ex. 5 at 306:20-307:4, Ex. 6)

> Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?
> A Yes. (Ex. 5 at 307:10-14, Ex. 6).

34. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Ex. 2 at 2:58-61).

### C. I Disagree With Arthrex's Assertions Regarding the Purpose & Function of the First Fiber-Forming Materials

#### 1. The 446 Patent Does Not State that the Only Function of the First Fiber-Forming Materials Is to Improve Pliability

35. I disagree with Arthrex's assertion that the only function of the first fiber-forming materials described in the 446 Patent is improving pliability. As I explained in my first report at ¶55 and my rebuttal report at ¶10, the 446 Patent describes a broader function for the first fiber-forming materials that is not limited:

- "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which makeup the yarns" (*id*. at 2:49-52);

- "it is possible to tailor the physical . . . properties of the braid by varying the type and proportion of each of the dissimilar fiber forming used" (*id.* at 2:58-62);

- in preferred embodiments the first fiber-forming materials can contribute other properties including "pliability," "compliance" and "surface lubricity" (*id.* at 4:11-13).

As I explained above, the properties of the first fiber forming materials are much broader than just pliability.

2. **The 446 Patent Does Not Describe the First Fiber-Forming Materials As "Relatively Weak"**

36. I disagree with Arthrex's assertion that the 446 Patent describes the first fiber-forming materials as "relatively weak," (Arthrex Br. at 11) and that this is a basis for finding that the differences between the first fiber-forming materials and FiberWire's braided PE are substantial. I disagree because the 446 Patent does not describe the first fiber-forming materials as "relatively weak." For example, the 446 Patent describes PE, which includes UHMWPE, as a first fiber-forming material, and UHMWPE was known to have certain strength attributes, such as tensile strength. Likewise, the 446 Patent describes polypropylene (PP) as a first fiber-forming material, and it is known to have certain strength attributes, namely tensile strength. This is described in the literature. For example, *Marks' Standard Handbook for Mechanical Engineers*, a well known reference, describes polypropylene fibers as having a breaking tenacity of 4.0-7.0 gpd (Ex. 10). Further, U.S. Patent No. 4,413,110 describes certain polypropylene fibers as having a tenacity of at least about 8 gpd (Ex. 11 at 2:7-11). Also, the *Production and Applications of Polypropylene Textiles* states on page 54 that the breaking tenacity of polypropylene fibers is over 500 $mNtex^{-1}$ (Ex. 12). Thus, certain polyethylene and polypropylene fibers are not "weak"

in tensile strength. Thus, I disagree that the 446 Patent describes the first-fiber forming materials as being "weak."

37. Arthrex seems to indicate that the first fiber-forming materials are all necessarily "weak" in tension when compared to the second fiber-forming materials and that only the second set of yarns can impart strength (Arthrex Br. at 11). Even assuming that Arthrex means weak in tension, I disagree with this statement. Arthrex's statement is incorrect because polypropylene fibers, one of the first fiber-forming fibers, were known to have strength on the same order of magnitude of nylon and PET fibers, two of the second fiber-forming materials. For example, *Marks' Handbook* describes polyester fibers, which I read as including PET, as having a breaking tenacity of 4.4-7.8 gpd, and nylon 6,6 fibers as having a breaking tenacity of 4.6-9.2 gpd (Ex. 10). Further, the *Production and Applications of Polypropylene Textiles* states on page 54 states that the breaking tenacity of polyester fibers, which I read as including PET, is 350 $mNtex^{-1}$ (Ex. 12). Using this information, PP has a breaking tenacity in the range of other well known relatively high-strength fibers such as polyester (PET) and nylon. Further, one fiber manufacturer describers the tensile strength of two first fiber-forming materials, PVDF and PP, as having about the same tensile strength as two of the second fiber-forming materials, nylon and PET. For example, it states that monofilament PVDF has a tenacity of 4.71 gpd, two monofilament polypropylenes have breaking strengths of 3.0 and 4.0 gpd, two monofilament polyesters (which I read as PET) as having a breaking strength of 4.5 or 6.0 gpd, and nylon monofilaments as having a breaking strength of 4.5-6 gpd (Ex. 13; *see also* Ex. 14). Consequently, the first fiber-forming materials are not all "weak" in tension in comparison to the second fiber-forming yarns, and it would be incorrect to read the 446 Patent as stating that only the second set of yarns imparts tensile strength, as Arthrex incorrectly suggests.

38. I understand that Arthrex asserts that "the admitted purpose of UHMWPE in FiberWire is to add strength to the braid" and implied that is UHMWPE's only function (Arthrex Br. at 11). I disagree with this assertion because it is an oversimplification and a misunderstanding of the many different properties that a material can provide. As I explained in my rebuttal report at ¶¶24-27 and here above at ¶17, FiberWire's PE is lubricous, and therefore it enhances other FiberWire properties such as handleability, pliability, and surface properties. Arthrex's argument seems to attribute all of FiberWire's strength to FiberWire's PE. I disagree with this assumption. FiberWire's PET also contributes to FiberWire's strength properties, including knot holding strength properties (Ex. 4 at 1:24-26, 29; 2:50-52; Ex. 3 at 103:19-104:15). Further, even if FiberWire's PE's only function is to add tensile strength as Arthrex incorrectly asserts, it is my opinion that the first fiber-forming materials, such as PP and PVDF, function to add tensile strength. Therefore, the differences between UHMWPE and the first fiber-forming materials are insubstantial.

39. Also, Arthrex's assertion that Ultra high molecular weight PE is "strong" is a simplification of material properties. Ultra high molecular weight PE is "weak" in at least two ways, compression and knot holding properties when braided in certain structures, which I explained above with reference to Mr. Grafton's work and Arthrex's 234 Patent. Thus, even if is Arthrex is correct (which it is not) that the 446 Patent describes the first fiber-forming materials as "weak" and braids made from them as weak, ultra high molecular weight PE satisfies these requirements because it too is "weak."

### D. Even if Arthrex is Correct Regarding the Teachings Of the 446 Patent, There Is Still Infringement Under the Doctrine of Equivalents

#### 1. Even if Arthrex is Correct That The Function of the First Fiber-Forming Materials Is To Improve Pliability, FiberWire Infringes Because FiberWire's PE Improves Suture Pliability

40. I understand that Arthrex asserts that that the only function of the first fiber-forming materials is to "improve overall pliability of the suture" and FiberWire's PE does not perform this function because it is a stiff material (Arthrex Br. at 10). For the reasons stated above, I disagree that this is the function of the first fiber-forming materials. But even accepting this function, there is still infringement under the doctrine of equivalents because FiberWire's braided ultra high molecular weight PE improves overall pliability of the suture. As I explained in ¶25 of my rebuttal report, ultra high molecular weight PE is lubricous and contributes to braid pliability because it allow the fibers to slide past each other when bent. In constructing FiberWire, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. 3 at 68:25-70:12). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliability, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. UHMWPE has many uses. "General purpose" PE and UHMWPE can be substituted for each other, depending on the application.

41. Arthrex's argument appear to be based on confusing two discrete concepts, *material* stiffness and *braid* stiffness. *Material stiffness* is a material property that is dependent upon just the material properties, like the tensile and compressive modulii, and cross-sectional shape of the specimen, which in this instance is a fiber. In contrast, *braid stiffness* for a multifilament

structure like FiberWire is dependent upon many factors including the number of filaments, the modulus of elasticity in tension and compression, the fiber-to-fiber mobility, and the individual moment of inertia of each filament, the manner in which the materials are braided, and material lubricity. As the 446 Patent explains, material lubricity permits fiber-to-fiber mobility, so that when the braid is bent the fibers can easily bend and slide past other fibers. Thus, even accepting that ultra high molecular weight PE is "stiff," Arthrex's counsel assertions that it does not improve overall braid pliability are just wrong.

42. Arthrex's argument is basically the same concept that I addressed before when Arthrex's expert incorrectly assumed that FiberWire is a monofilament structure. As I explained previously, FiberWire is neither a monofilament nor a pure multifilament structure. Arthrex's statement that FiberWire's PE does not improve braid pliability basically makes a similar mistake and incorrectly assumes that FiberWire is a monofilament type structure.

## IV. Under Arthrex's Definition of "Consisting Essentially Of," FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

43. As I understand the law, because the 446 Patent claims recite the phrase "consisting essentially of," if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the "basic and novel characteristics" of the claimed suture. I understand that Arthrex contends that the "basic and novel characteristics" of the suture claimed in the 446 Patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Arthrex Br. at 13). Arthrex asserts that that FiberWire's coating materially affects this novel and basic characteristic because it materially affects handleabilty and knot tie down properties (Arthrex Br. at 13-14). I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties

described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a "material" affect on the basic and novel characteristics; and (iii) Dr. Burks' tests and analyses show that FiberWire's coating does not materially affect handleability. I describe each of these three points below.

### 1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

44. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface "lubricant" (Ex. 15).

45. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex's development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. 3 at 52:24-53:7). The

homogeneous UHMWPE braid was too lubricous to "hold a knot" (*id*. at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good "strength" properties (Ex. 3 at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (*id*. at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. 16). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. 16; Ex. 3 at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the

prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?
A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. 3 at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. 3 at 68:25-70:12). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliablity, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

46. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr. Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the [E]thicon sample)" (Ex. 6) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. 6). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

Q. I would like to know what you mean by in your

letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?

A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
Q. Wait a second. You said optimization of two materials.
A. (Witness nods head affirmatively).
Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
A. During -- during the -- during that period of time, yes.
Q. So you were balancing off the properties of each material to try to get the optimum properties --
A. Tensile strength.
Q. To get the optimum tensile strength?
A. (Witness nods head affirmatively).
Q. What about knot security?
A. Yes.
Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
A. Yes.
Q. Any other properties? Knot tiedown?
A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
Q. So you were varying type and proportion of the materials to optimize all these properties in the product?
A. Yes.

(Ex. 3 at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?
A. All materials used.

(Ex. 17 at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

47. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasureable (Ex. 5 at 119:5-9; Ex. 8 at 94:2-9; Ex. 18 at 48:1-50:16; Ex. 19 at ARM002104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed[3] and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters per minute (Ex. 5 at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. 5 at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. 5 at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. 5 at 95:14-17). The process is then repeated. I have measured

[3] Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DMI Exhibits 284, 342, and 285, Exs. 20, 21, and 22, respectively). I determined that the linear density of DMI Ex. 284 (uncoated) is 2393 denier, DMI Ex. 342 (coated once) is 2474 denier, and DMI Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of DMI Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated DMI Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from DMI Ex. 342. Thus, the total pick-up of Ex. 285 over DMI Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Ex. 15).

48. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire

has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

49. I note that Arthrex does not address the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, Arthrex only asserts that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as Arthrex defined the novel and basic characteristics. Rather, the relevant issue as Arthrex framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Arthrex Br. at 13). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

### 2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

50. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Arthrex, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Arthrex.

51. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties

attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. 2 at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (*id*. at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

52. I disagree with Arthrex that FiberWire's coating has a "material" effect because Arthrex basically *excludes* coated sutures from the 446 Patent claims. But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

> If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to ***further*** improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. ***Most preferably***, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating ***may be*** eliminated saving expense as well as avoiding the associated braid stiffening.

(*id*. at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

53. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Arthrex attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set

of continuous and discrete yarns (*id*. at 2:40-42). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (*id*. at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (*id*. at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. 8 at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. 2 at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. 20, 21, and 22. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as is shown by its product development (Ex. 3 at 68:25-70:13). The 446 Patent teaches "to tailor" the physical braid properties "by varying the type and proportion of each of the dissimilar fiber forming materials used" (Ex. 2 at 2:58-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. 3 at 68:25-70:13). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. 2 at 6:9-10). Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can "***further***" improve the handleability of the suture (Ex. 2 at 6:5-18) (emphasis added). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. 2 at 6:11-13). As shown by the SEM's of the FiberWire, the fibers are not bonded together (Exs. 20, 21 and 22). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

54. I further disagree with Arthrex's focus on FiberWire's coating with reference to defining what is "material" because the 446 Patent is not about "coating" or eliminating "coatings." Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. 2 at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (*id*. at 1:32-43), a PTFE coating (*id*. at 1:43-54), a monofilament like surface on a multifilament braid (*id*. at 1:55-2:2), and an elongated core (*id*. at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (*id*. at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

55. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties "attributable to the specific properties of the dissimilar fiber-forming materials" (*id*. at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be "improved" by a coating (*id*. at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent's description of the invention shows that it does not consider coating, as used on FiberWire, to have a "material" effect on the basic and novel characteristics of the claimed suture.

### 3. Dr. Burks' Testimony Supports My Opinion that the Effects of FiberWire's Coating Are Not Material

56. I have reviewed Dr. Burks' testimony and deposition transcript. I understand that he considered the differences between the treated and untreated sutures as "subtle" and "pretty close" (Ex. 23 at 87:7-13; 88:1-3; 96:18-19; 98:18-21). He also stated that he could not "clearly feel a difference" (*id*. at 88:9-10). This supports my opinion that any purported differences are not material.

57. Also, Dr. Burks testified that wearing gloves would make a difference in whether he, as a very experienced surgeon, can even tell the difference between the treated and untreated samples (*id*. at 96:24-97:5; 72:1-73:6). In fact, he testified that he may not have been able to tell a difference if he used just gloves (*id*. at 73:9-14; *see also* 96:24-97:5). He testified that using gloves made a difference in the feel of a suture (*id*. at 72:7-8). I understand from Dr. Burks that he wears gloves when using FiberWire in surgery (*id*. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

58. I note that Arthrex criticizes for me for not remembering at my deposition that I had considered certain information in my analyses that Dr. Mukherjee had considered. But after reading Arthrex's criticism, I consulted my Rebuttal Expert Report and it refreshed my memory that I had considered those materials. As I explained in ¶54 of my rebuttal report, I disagree that these documents are relevant to the analysis because they discuss products and coatings that are different than FiberWire. It is my opinion, that the effect of FiberWire's coating on FiberWire cannot be determined with reference to other products with different coatings, different applications of coatings, and different suture constructions. Although I did not recall at my deposition that I had reviewed these documents, I do now recall reviewing them to determine

whether they discussed FiberWire's coating, and they do not. I have provided three reports in this case and reviewed thousands of pages of documents. My deposition was on July 26-27, 2006, just over three months since I finalized my rebuttal report. Although I did not recall that one paragraph from my three reports at my deposition, Arthrex's counsel did not ask me to review that paragraph when asking questions about these documents. If he had, it would have refreshed my memory on the issue.

## V. Under Mitek's Definition of the Novel And Basic Characteristics, FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

59. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

60. I understand that Mitek has asserted that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the

second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (Ex. 26 at ARM001976).

61. The '446 Patent specifically contemplates, in the "Detailed Description of the Invention," that the braided sutures of the invention can be coated (Ex. 2 at 6:5-21). The '446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (*id.* at 6:9-11). Thus, the '446 Patent's description of the invention as contemplating coatings supports my opinion that FiberWire™'s and TigerWire™'s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the '446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.[4]

62. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Ex. 21 (DMI Ex. 284), Ex. 22(DMI Ex. 342), Ex. 23 (DMI Ex. 285).

63. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

[4] My opinion is further supported because the '446 Patent claims a "suture." I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

64. It is my expert opinion and observation that the coating only appears on the surface of the braid.

I declare under penalty of perjury that the foregoing is true and correct.

Date Executed: September 1, 2006 /s/

# BROOKSTEIN DECLARATION EXHIBIT 1

David Brookstein, Sc.D.
Dean and Professor of Engineering
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Philadelphia, PA 19144
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# Curriculum Vitae

## Education:

- Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.
- Bachelor of Textile Engineering, Georgia Tech, 1971.
- Harvard University School of Business Summer Program on Research Management, 1990.
- Harvard University Graduate School of Education MLE Summer Program, 1998

## Professional Experience:

Philadelphia University

1994 - Present — Dean and Professor of Engineering
School of Textiles and Materials Technology (soon to be the School of Engineering and Textiles)

Chief academic and financial officer for a school with undergraduate majors in industrial and systems engineering. textile engineering (ABET accredited), textile technology, textile design, fashion design and fashion industry management. Master of Science programs are offered in textile engineering, textile design, textile marketing, global textile marketing, on-line MBA in textile and apparel marketing and fashion-apparel studies. Developed first Philadelphia University program, - Ph.D. in textile engineering and science. Principal Investigator for largest outside funded research grant received by Philadelphia University, $2.7 million DoD grant for the Laboratory for Engineered Human Protection. Philadelphia University Program Leader for the National Textile Research Center, a $10 million/annum grant for a consortium of universities that include Auburn Unviersity, Georgia Tech, North Carolina State University, Clemson University, UMASS-Dartmouth, Cornell University and University of California-Davis. Led the development of the Philadelphia University Research Center in the Manayunk section of Philadelphia.

Harvard University
2002 – 2003 Visiting Scholar
Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences)

Albany International Research Co. - Mansfield, MA
1992 - 1994 Associate Director
1983 - 1992 Assistant Director
1980 - 1982 Senior Research Associate

Directed all activities of the professional engineering group responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. Accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous preforms for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures. Engineering innovations led to 11 US patents and many other inventions protected by trade secret. Member of the senior management staff of the organization.

Northeastern University - Boston, MA
1981-1983 Adjunct Professor in Mechanical Engineering

Taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

Georgia Institute of Technology, College of Engineering
1975 - 1980 Assistant Professor of Textile Engineering

Taught and conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems. Obtained substantial funding from US DOE and US DOD. Active participant in College of Engineering co-op undergraduate programs.

**Outside Professional Activities**:

- Advisory Board of the College of Engineering, Georgia Tech.
- Member of the University City Science Center Research Provost Roundtable
- Adjunct Full Professor, North Carolina State University
- President, The Fiber Society (1996)
- Chairman, Textile Engineering Division-American Society of Mechanical Engineers (1994-1996)
- Research Associate - Textile Research Institute/Princeton
- Member of the Manufacturing Technology Operating Group of the ASME
- Peer Reviewer for ASME Fellows

**Memberships:**

- American Society for Engineering Education
- Council of Engineering Deans
- Institute of Industrial Engineers
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- American Conference of Academic Deans
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994,
- President (1996)
- SAMPE - Society for Advanced Materials and Process Engineering
- The Textile Institute

**Awards and Honors:**

- ASME – Fellow, 1995
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994, President, 1996
- The Textile Institute (United Kingdom) – Fellow, 1992
- Georgia Tech Academy of Distinguished Engineering Alumni, 1999
- Techtextil Innovation Prize, 1993 (Germany)
- ASTM Harold Dewitt Smith Award, 1998

**Publications:**

"Deductions about the False-Twist Process from Observations of the Variation of Torque on Detwisting at Heat Set Yarn," with Backer, S., and Thwaites, J.J., Journal of the Textile Institute, 67, p. 183-186, 1976.

"Transient Threadline Behavior in False-Twist Texturing," with Thwaites, J.J., and Backer, S., Journal of the Textile Institute, 67, 1976.

"Mechanics of Texturing Thermoplastic Yarns: Part III. Experimental Observations of Torsional Behavior of the Texturing Threadline for Pre-Drawn PET Yarns," with Backer, S., Textile Research Journal, 46, pp. 802-908, 1976.

"Mechanics of Texturing Thermoplastic Yarns: Part V. Steady State Mechanics of Drawing Texturing," Textile Research Journal, 47, p. 256-266, 1977

"Material-Process Interactions During False-Twist Texturing," with Backer, S., Journal of Applied Polymer Science: Applied Polymer Symposium, 31, p. 63-82, 1977.

"Mechanics of Texturing Thermoplastic Yarns: Part VI. Transient Mechanics of Draw Texturing," with Backer, S., Textile Research Journal, 48, p. 198-218, 1978.

"On the Mechanics of Draw Texturing," Journal of Applied Polymer Science: Applied Polymer Symposium, 33, p. 197-202, 1978

"Energy Consumption and Conservation: Textile Drying," ACS Symposium Series, 107/17, 1979

"All That Glitters is Not Gold," Textile World, October 1979

"Energy Conservation in the Textile Industry," ERDA - Phase I Report, DOE, April, 1977, Quarterly Reports, 1976 to 1977, Final Report.

"Processing of Pitch-Based Staple Carbon Fiber," Union Carbide Corporation, November 1977, Final Report.

"Low Thermal Conductivity of PAN-Based Carbon Fiber, Hercules, Inc., Monthly Reports and Final Report

"Development and Demonstration of Energy-Conserving Drying Modifications to Textile Processes," U.S. DOE Monthly Reports.

"Optimization of Sucker Rod Pumping Using Novel Material-Systems Concepts," with Skelton, J. and Dent, R., Proceedings of the Sixth Symposium of Engineering Applications of Mechanics, Petroleum Society of CIM, 1982

"Mechanical Characterization of Braided Cylinder," with Tsiang, T.H., and Dent, J., Proceedings of the 29th SAMPE Meeting, 1984.

"Design and Development of a High Stability Truss Chord," with Helmke, R., and Kominos, C., Proceedings of the 30th SAMPE Meeting, 1985.

"Load-Deformation Behavior of Composite Cylinders with Integrally-Formed Braided and Machined Circular Holes," with Tsiang, T.H., Journal of Composite Materials, 19, September 1985.

"Braided Composites: Attachment Considerations, Proceedings of the Composites in Manufacturing, Los Angeles, CA, January 1986.

"Foam Assisted Drying,: with Skelton, J., Petterson, D.R., and Lauchenauer, F., Proceedings of the International Drying Symposium, Cambridge, MA, August 1986

"Joining Methods of Advanced Braided Composites," Composite Structures, 6, p. 87-95, 1986

"Structural Applications of Advanced Braided Composites," Proceedings of the SPE Advanced Polymers Composites Division, November 1988.

"Processing Advanced Braided Composite Structures," Proceedings of the WAM of ASME, Materials Division, November 1988.

"Interlocked Fiber Architecture: Braided and Woven," Proceedings of the 35th SAMPE Meeting, April, 1990.

"Evolution of Fabric Preforms for Composites," Journal of Applied Polymer Science: Applied Polymer Symposium, 47, p. 487-500, 1991.

"A Comparison of Multilayer Interlocked Braided Composites with Other 3-D Braided Composites," 3rd International Techtextil Symposium, 14-16, May 1991, Frankfurt.

"On the Mechanical Behavior of 3-D Multilayer Interlock Braided Composites," with Preller, T., and Brandt, J., DASA-Deutsche Aerospace, Proceedings of NASA Fiber-Tex '92.

"The Evolution of 3-D Composites," Fifth European Conference on Composite Materials," 7-10 April 1992, Bordeaux.

"The Solid Section Multilayer Interlock Braiding System," 4th International Techtextil Symposium, 4 June 1992, Frankfurt.

"On the Mechanical Properties of Three-Dimensional Multilayer Interlock Braided Composites, TECHTEXTIL Symposium, 1993, Frankfurt.

"3-D Braided Composites-Design and Applications," Sixth European Conference on Composite Materials," 20-24 September 1993, Bordeaux

"Concurrent Engineering of 3-D Textile Preforms for Composites," International Journal of Materials and Product Technology, Vol. 9, Nos 1/2/3, 1994.

"Advanced Textile Airbeams for Temporary Shelters, 6th TECHTEXTIL Symposium, 1994, Frankfurt.

"Physical Properties of Twisted Structures" with Ning Pan, Fiber Society Symposium, Asheville, NC, 1998.

**PATENTS Consisting of Original Contributions to field of engineering:**

1. U.S. Patent 4,290,170 "Device for Aligning and Attenuating Fiber Mats," A device for producing aligned carbon fiber webs for use in composites.

2. U.S. Patent 4,497,866 "Sucker Rod," An elliptical cross-section braided composite rod for pumping oil.

3. U.S. Patent 4,602,892 "Sucker Rod," A braided composite rod and coupling for pumping oil.

4. U.S. Patent 4,841,613 "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.

5. U.S. Patent 4,909,127 "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.

6. U.S. Patent 5,004,474 "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.

7. U.S. Patent 5,357,839 "Solid Braid Structure" A 3-D system for producing braids.

8. U.S. Patent 5,358,758 "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.

9. U.S. Patent 5,411,463 "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.

10. U.S. Patent 5,501,133 "Apparatus for Making a Braid Structure" A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.

11. U.S. Patent 5,697,969 "Vascular Prosthesis and Method for Implanting" A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

**Non-patentable trade secret inventions developed at Albany International Research Co.**

1. Fiber-reinforced composite rocket igniter for Small ICBM and Pegasus Air-Launched Vehicle
2. Specialty vascular grafts and bio-absorbable orthopedic implants
3. Flexible air-beam for military structures
4. New method for drying paper during the papermaking process
5. Complex, reduced delamination rocket motor exit cones

# BROOKSTEIN DECLARATION EXHIBIT 2

US005314446A

# United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] Inventors: Alastair W. Hunter, Bridgewater; Arthur Taylor, Jr., Plainfield, both of N.J.; Mark Steckel, Maineville, Ohio

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 838,511

[22] Filed: Feb. 19, 1992

[51] Int. Cl.[5] ..... D04C 1/00

[52] U.S. Cl. ..... 606/231; 606/228; 87/7; 87/9; 428/370

[58] Field of Search ..... 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] References Cited

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 3,187,752 | 6/1965 | Glick | 128/335.5 |
| 3,463,158 | 8/1969 | Schmitt et al. | 606/228 |
| 3,527,650 | 9/1970 | Block | 117/7 |
| 3,636,956 | 1/1972 | Schneider | 128/335.5 |
| 3,942,532 | 3/1976 | Hunter et al. | 128/335.5 |
| 4,043,344 | 8/1977 | Landi et al. | 128/335.5 |
| 4,047,533 | 8/1977 | Perciaccante et al. | 128/335.5 |
| 4,052,988 | 10/1977 | Doddi et al. | 128/335.5 |
| 4,141,087 | 2/1979 | Shalaby et al. | 3/1 |
| 4,470,941 | 9/1984 | Kurtz | 264/136 |
| 4,624,256 | 11/1986 | Messier et al. | 128/335.5 |
| 4,946,467 | 8/1990 | Ohi et al. | 606/228 |
| 4,959,069 | 9/1990 | Brennan et al. | 606/228 |
| 4,979,956 | 12/1990 | Silverstrini | 623/13 |
| 5,116,360 | 5/1992 | Pinchuk et al. | 623/1 |
| 5,147,400 | 9/1992 | Kaplan et al. | 623/13 |

FOREIGN PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 2949920 | 3/1981 | Fed. Rep. of Germany | A61F 1/00 |
| WO86/00020 | 1/1986 | PCT Int'l Appl. | A61L 17/00 |
| 2082213 | 8/1980 | United Kingdom . | |
| 2218312A | 11/1989 | United Kingdom | A01K 91/00 |

*Primary Examiner*—George F. Lesmes
*Assistant Examiner*—Chris Raimund
*Attorney, Agent, or Firm*—Hal Brent Woodrow

[57] ABSTRACT

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

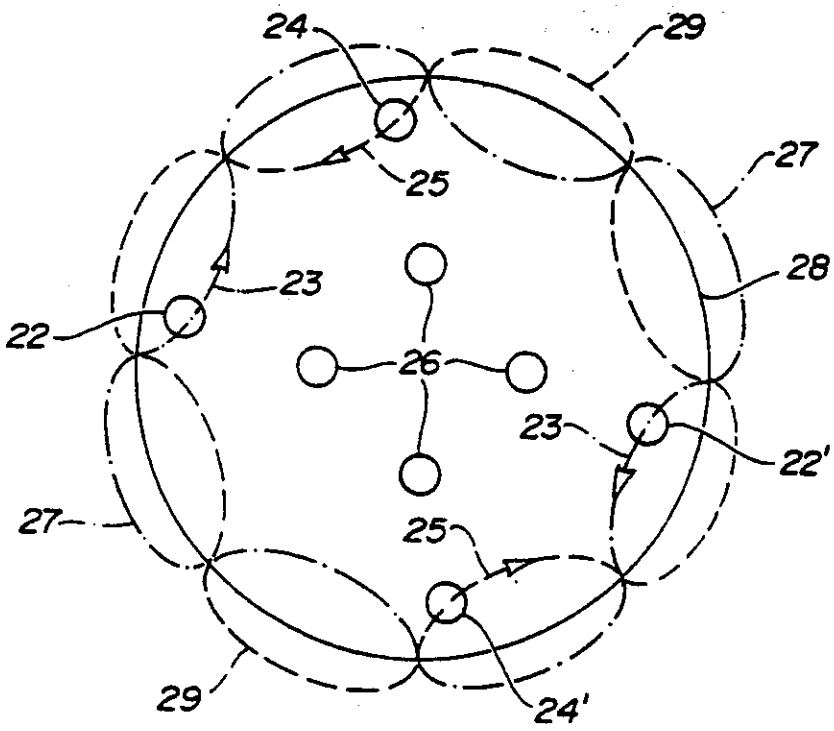


FIG-2

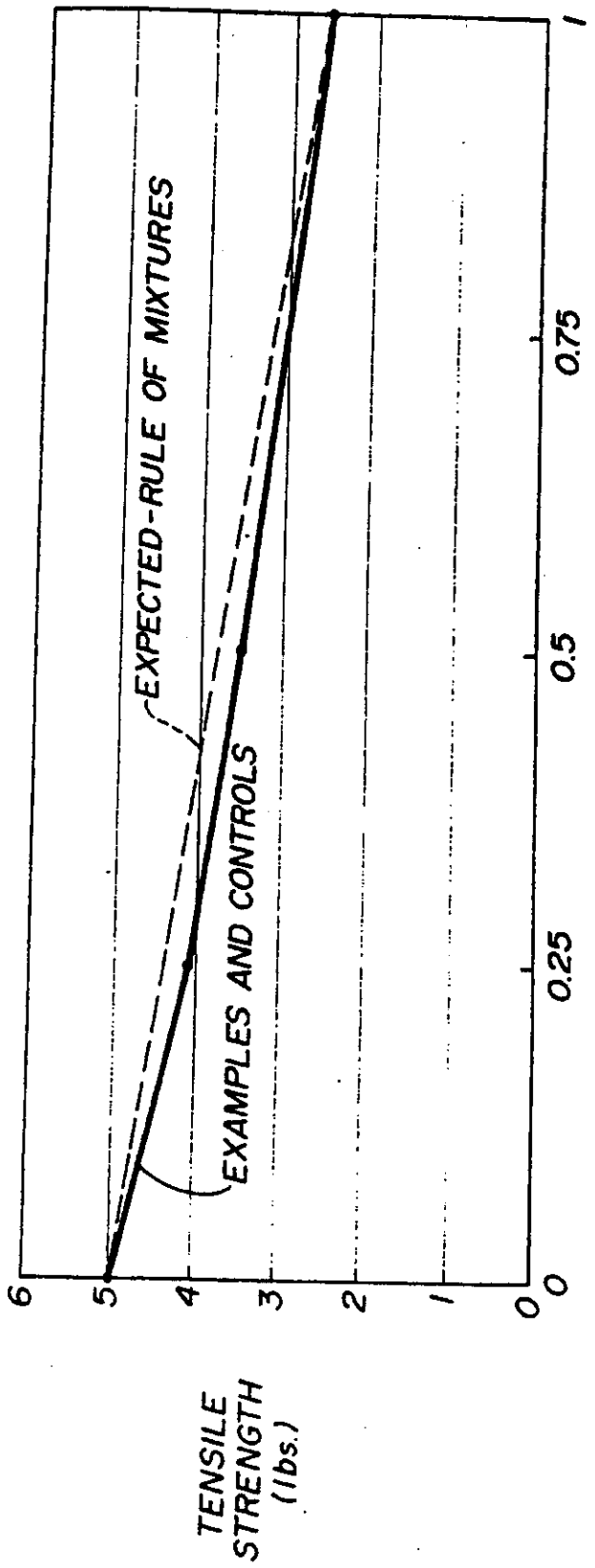
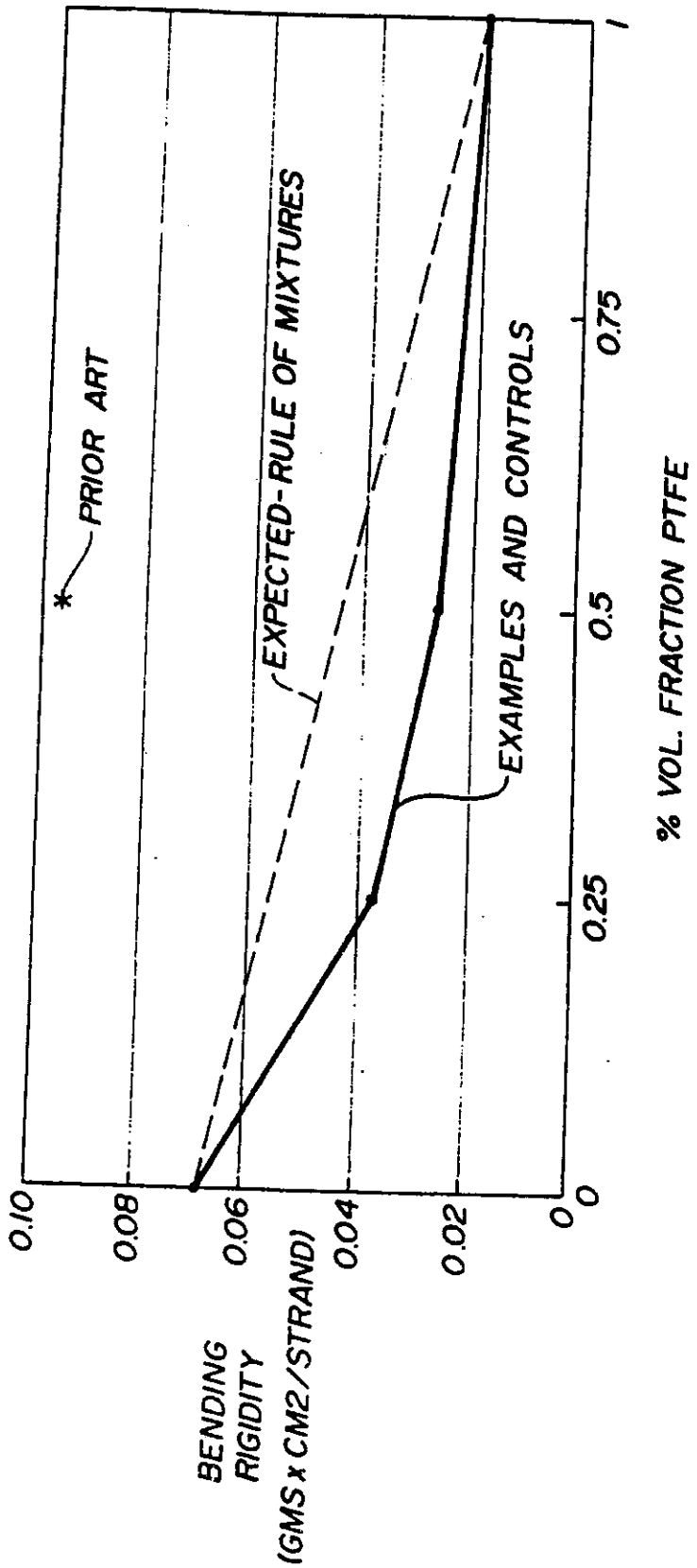

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0
0.25
0.5
0.75
1
BENDING RIGIDITY (GMS x CM2/STRAND)
% VOL. FRACTION PTFE

# STERILIZED HETEROGENEOUS BRAIDS

## BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.



Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

## SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

## DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

## EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

| | USP DIAMETER (mils) | TENSILE STRENGTH (lbs) | KNOT STRENGTH (lbs) | BENDING RIGIDITY (gm × cm²) | KNOT STABILITY (# of throws) |
|---|---|---|---|---|---|
| CONTROL I | 10.68 | 4.98 | 3.14 | 0.0680 | 4 |
| CONTROL II | 9.11 | 2.58 | 2.04 | 0.0196 | 7 |
| EXAMPLE I | 9.71 | 3.55 | 2.41 | 0.0257 | 5 |
| EXAMPLE II | 10.35 | 4.10 | 2.67 | 0.0371 | 5 |
| PRIOR ART I | 8.81 | | | 0.0966 | |

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where $P_c$ is a composite property (such as tensile strength or modulus), $P_a$ and $P_b$ are the properties of the components a and b, and $Vf_a$ and $Vf_b$ are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table I and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.



6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

# BROOKSTEIN DECLARATION EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

Q. And you don't recall whether or not the polyester suture from Arthrex had a core?
A. You said from Arthrex. You're talking about Pearsalls now?
Q. I'm sorry. The 100 percent polyester suture from Pearsalls, did it have a core?
A. Don't know.
Q. Don't know? And the polyester that was braided in the polyester suture from Pearsalls, do you know what type of polyester that was?
A. No.
Q. When's the first time that you went over to England to visit Pearsalls?
A. Don't remember.
Q. How many times have you been over to England to visit Pearsalls?
A. Three to five.
Q. When you were involved in the process of selecting this polyester suture from Pearsalls, did you go over and visit Pearsalls?
A. No.
Q. No? At some point, Arthrex -- Let me back up.
What was the next suture that you can remember Arthrex selling after the polyester?
A. Jenzyme Tevdek.



Q. Were you involved in the selection of the Tevdek suture?
A. What do you mean involved? Primary identification or selection or did I know the company? Or you are going to have to -- When you say involved, sir, I need to know exactly what you're talking about.
Q. Okay. Were you involved in the selection of this Tevdek suture from Jenzyme?
MR. SOFFEN: Objection; vague. He just said he doesn't have --
A. I'm not sure -- Again, when you say involved, I'm involved in this, but I'm not asking the questions. So you need to -- when you say involved, what does involved mean exactly? I -- I was the engineer that was responsible for saying yes, this is a product that meets engineering specifications.
Q. Okay. Did you recommend that Arthrex sell the Tevdek sutures?
A. From an engineering standpoint, the material met the specification or engineering requirements to be used with a suture anchor.
Q. And what were the engineering requirements that you reviewed Tevdek suture for?
A. Knot strength, tensile strength, color, biocompatibility. You know. It's -- on and on.



Q. Knot tiedown? Is that one of the considerations?
A. Knot -- knot strength.
Q. Was knot tiedown one of the considerations that --
A. Well, obviously, if you are going to tie a knot, I mean, it's going to be tied down to something. Yes. The makeup of the suture anchor, so, yes.
Q. So the answer is yes?
A. Yes.
Q. Okay. When you were selecting the Pearsalls suture, was knot strength a consideration?
A. Of course.
Q. And when you were selecting the Pearsalls suture, was tensile strength a consideration?
A. Yes.
Q. When you were selecting the Pearsalls suture, was knot tiedown a consideration?
A. Knot tiedown, knot strength are -- in my thinking are similar or the same thing.
Q. Same thing?
A. (Witness nods head affirmatively).
Q. What do you mean -- In your thinking, when you say knot strength, what do you mean?
A. Surgeon's application is to tie a knot. That is affixing it to -- in approximation to tissue to bone.



That is knot tiedown. And there's a knot placed in the suture, so -- so tying a knot and knot tiedown are the same things as far as I'm concerned.
Q. Okay. You just said tying a knot and knot tiedown is the same thing. My question was slightly different. Knot strength versus -- What is your understanding of knot strength?
A. It's the mechanical tensile of the suture's ability to -- to, after tying a knot, before breakage.
Q. Did you generally consider knot strength to be determined by tying a knot in a suture and testing it on a tensile --
A. Yes.
Q. -- testing machine?
A. Yes.
Q. How about knot tiedown? Is that --
A. We didn't test for knot tiedown.
Q. So you -- Before, you said knot strength and knot tiedown were the same thing.
A. That's why I said that we tested for knot strength -- okay -- for -- of tying a knot. And I consider those the same things. So we didn't -- we didn't test specifically for tying soft tissue down. We tested the knot as tying a knot versus -- what the standard calls for and doing a pull test on it.

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Q. Let me back up to make sure this is clear. Knot strength versus knot tiedown. In your mind, are they the same thing or are they different?
A. I'm not sure I understand your question. Say that again.
Q. Sure. Knot strength --
A. Mmm-hmm (affirmative).
Q. -- which I think you testified that you understood to be tying a knot in a suture and pulling it on a tensile machine -- tensile tester machine to determine the strength at which the knot will break; right?
A. Yes.
Q. Okay. Then there's another term called knot tiedown, and I'm trying to understand whether, in your mind, you think that's the same as knot strength or do you use that term to mean something else?
A. They're closely related.
Q. And how are they related?
A. When you have a knot tiedown, you've tied a knot. The strength of the knot is going to affect the ability to hold -- to approximate the tissue in the tiedown area that you're talking about.
Q. If the knot had a good tiedown or a bad tiedown, what do you mean by that?

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A. Its ability to approximate the tissue and hold it in place through biomechanical forces.
Q. So that's related to knot strength, but it's not necessarily the same thing; is that the way you're using the term?
A. Yes.
Q. The way I heard you describe knot tiedown was you said the ability to approximate the tissue and hold it into place through biomechanical forces.
A. (Witness nods head affirmatively).
Q. When you say ability to approximate the tissue, what do you mean by that?
A. Shift tissue in the position that the surgeon would like for it to be on the bone.
Q. Shift tissue; did you say?
A. Yes.
Q. S-H-I-F-T?
A. Yes.
Q. So the knot's moving the tissue?
A. The suture is holding -- the suture loop with the knot in it, is holding the tissue in the position that the surgeon would like for it to be on bone.
Q. That's taking the place of the tissue? When you say approximate the tissue, how is it approximating tissue?

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A. It's -- The tissue is here. The location the surgeon wants it here. The suture loop as it is tied moves the tissue into position.
Q. Holds it there?
A. Yes.
Q. And what -- what biomechanical forces were you referring to?
A. Forces on the glenohumeral joint.
Q. In a knot strength test, it's the forces are being applied and generally in one direction; correct?
A. Yes.
Q. The biomechanical force that you are referring to in this knot tiedown, the forces are coming from different directions; right?
A. Yes.
Q. Okay. When you are referring to knot tiedown then, you're referring to -- you're referring to it in a sense as a strength?
A. Are you finished? Is that the question?
Q. Right.
A. I don't believe -- Say it again then.
Q. Sure. Knot tiedown, the way you're referring to it, it's a strength then? It's kind of like -- because knot strength would be measured in p.s.i.
A. I said that's one of the attributes of it.

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That's not the total attribute of it. I mean it's to approximate tissue into position is knot tiedown.
Q. Well, what else would be included?
A. I just told you. Approximate tissue, strength.
Q. So the strength would -- I understand the --
A. The size of the knot bundle. You know, there's --
Q. Size of the knot bundle?
A. Yes.
Q. What do you mean by that?
A. How large the knot is once it has been tied and cut.
Q. So knot tiedown includes the size of the knot bundle?
A. Yes. You know, the knot tiedown -- I want to say this -- that's not a term that we specifically use, so it's a little bit foreign. I mean I don't -- I've never had a surgeon ask me about knot tiedown.
Q. Okay.
A. So I didn't -- your -- I'm not sure where you're going with this, but there's -- we did knot testing and we did straight pull testing of the suture so that your knot tiedown, I'm -- I'm not real sure what you're asking for there. I --
Q. Well --

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A. What's the date on this?
Q. The date on this is -- the last page is dated November 4th, 2005.
A. Okay. I want to quantify this then, because you're talking about a time period after I worked for the company, so when you -- when it says in here that I'm familiar with these products, it would be at the time I had left the company. And this is -- this was written after I left the company. So I can't totally say that I am familiar with those products under that.
Q. So you would agree that you were familiar with the state-of-the-art for surgical suture products as of the date you left Arthrex?
A. Define state-of-the-art, sir.
Q. State-of-the-art? Well, the general -- You don't have an understanding of what that means?
A. I want to understand what you mean in the context of this state-of-the-art.
Q. Okay.
A. I mean there's -- there's -- there's --
Q. This is from Pearsalls, so I can't tell you exactly what they mean, so ... Let me back up. When you were --
A. I was -- I was familiar with the competitive products on the market and what we offered and how they

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compared to the competitive products.
Q. Okay. And that was as of the date you left Arthrex?
A. Yes.
Q. Okay. And how long were you familiar with Arthrex's suture products and the competitive suture products that are in the marketplace?
A. When we started marketing the product, the sutures, until the time I left.
Q. Okay. So sometime when Arthrex began selling the suture from the supplier from New Mexico?
A. Yes.
Q. Okay. When Arthrex shifted from the Pearsalls suture to the Tevdek suture, was there any consideration to -- or for Arthrex designing its own suture?
A. No.
Q. Why not?
A. Because we could find a suture OEM that was available already. Why manufacture the suture when there's a readily available source?
Q. Now you said you tested for the Tevdek suture before it was selected; right?
A. Of course.
Q. And then it came back after it was selected, the response from surgeons was that it had low knot strength

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and tensile strength; right?
A. Yes.
Q. Didn't that come up in your testing?
A. I don't recall.
Q. What was your involvement in the development of FiberWire?
A. It was my idea.
Q. When you say it was your idea, what do you mean by that?
A. I'll give you -- Would you like the story on how FiberWire came about?
Q. Sure.
A. We were having issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon.
Q. Ethibond?
A. Ethibond. This was numerous complaints from friendly surgeons, not -- not a massive amount of complaints, but it was determined that the tensile strength of the suture was not as good as the Ethicon Ethibond suture.
Q. When you say friendly, do you mean friendly to Arthrex?
A. Yes. And I had gotten a phone call from a Dr.

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Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said it kind of jokingly. He said, "And I didn't even work out the day before."
And so he was tying to be nice about it, but bottom line was your suture sucks. Okay?
And so -- you know -- we're in a position where we need to find a suture that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.
One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra-high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.
I had Pearsalls, mainly through Brian, as being the manufacturing person --
Q. Brian Hallett?

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A. That's correct -- make some Size 2 braided material, send to me, and at the -- coincidentally, at the same time, I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who is a R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up.

We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.

So at that point in time, it looked like we would not be able to use an alternative material of ultra-high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.

I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra-high molecular weight polyethylene to enhance the or reduce the knot slippage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra-high molecular weight PE, of adding the PET, and his -- I'll never forget the e-mail. He thought that was a killer idea.

And so I had asked then at that time for Brian

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Hallett to make me samples up of using those two materials and -- and send to me. And we tested the materials, and now we had a product that had superior tensile strength and greater knot strength than any competitive product out on the market.

Q. Okay. If I could just back up to a couple of points that you mentioned to make sure I understand what happened here. The -- You said the idea began -- or I'm sorry. Back up. You said when this idea came up, you had already been to Pearsalls several times?

A. Mmm-hmm (affirmative).

Q. And you were familiar with --

A. Yes.

Q. And when this idea came up, you were familiar with how sutures were manufactured?

A. Yes.

Q. Okay. And what did you mean by that?

A. One of the products -- projects that I worked on was a bioabsorbable suture similar to what Ethicon sells as Panacryl, and the difference being this was 100 percent PLLA material. The -- so we worked on this for about a year -- I don't know the exact time -- with many trips over to Pearsalls to change the construct of the yarn to enhance the tensile properties of the material. And so at that time, I became familiar with how a suture is

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processed to make a braid.

Q. Okay. And how many times were you over in England?

A. I told you already. Three to five.

Q. Three to five.

A. Approximate.

Q. Is that total lifetime?

A. That's an approximate number total lifetime, yes.

Q. Have you been to other manufacturing facilities for sutures?

A. Jenzyme Tevdek.

Q. And how many times have you been there?

A. Once, I believe.

Q. And when you were at Jenzyme Tevdek, did you see the manufacturing processes for Tevdek?

A. It was a dog and pony quick courtesy through the facility.

Q. So when you came up with the idea for using ultra-high molecular weight polyethylene in a suture, did you -- you say you are familiar with how sutures are made?

A. I'm also a fisherman. There's -- you know -- fishing line is -- uses ultra-high molecular weight polyethylene as a material that's used for sport fishing, very high strength.

Pearsalls made fishing line. And so they had

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this material already available as a fishing line. So it was an easy conversion -- you know -- conclusion, conversion to say what if this is used as a suture material, because ultra-high molecular weight polyethylene is a totally inert material.

Q. When you saw that Pearsalls had been using ultra-high molecular weight polyethylene in fishing line --

A. Yes.

Q. -- do you know how it was being used in fishing line, what the construction was?

A. No.

Q. Was it a braided construction? Was it --

A. I can't tell you for sure, sir.

Q. You don't know?

A. I wasn't interested in buying fishing line, so I didn't look at the details of it.

Q. So you had -- Sitting here today, you can't tell me anything at all about how the fishing line that Pearsalls was making with ultra-high molecular weight polyethylene was constructed?

A. It went through their manufacturing processes in their company, but specifically how it was made, the constructs, I have no idea or the size.

Q. In other words, you have no idea if it was all

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ultra-high molecular weight polyethylene or if it was braided or --
A. It's been too long ago. I can't tell you that.
Q. And your idea was to use the ultra-high molecular weight polyethylene as a suture?
A. Yes.
Q. Okay. And you had Mr. Hallett make a Size 2, I think you said?
A. Yes..
Q. Okay. Can you describe the construction of that first --
A. I don't remember now. It's been too long.
Q. Was it all ultra -- ultra-high molecular weight polyethylene?
A. Initially, yes, as a test prototype material.
Q. Was it braided?
A. Yes.
Q. Was it an eight-carrier or a sixteen-carrier?
A. I don't remember.
Q. You said it was a Size 2 though?
A. Yes.
Q. So it was a Size 2 ultra-high molecular weight polyethylene braided suture that did not have PET?
A. For the initial prototype material, that's correct.

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Q. Okay. And it didn't have nylon or any other material braided with it?
A. No.
Q. So the initial prototype was a ultra-high molecular weight polyethylene braided suture prototype, if you will?
A. Yes. Size 2.
Q. Size 2. And was the initial prototype, was it coated?
A. I don't remember.
Q. Okay. Do you know if the initial prototype went through any other manufacturing process like stretching or heating, twisting?
A. I don't recall.
Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes.
Q. Okay. And you tested the initial prototype that was 100 percent ultra-high molecular weight polyethylene with Dr. Burkhart and Dr. Chen?
A. Dr. Casey Chen, correct.
Q. Okay. And the test that you conducted with Dr. Burkhart and Dr. Chen on the ultra-high molecular weight polyethylene was a knot strength test?
A. Knot security.

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Q. Knot security test?
A. Yes.
Q. Was that the test we drew in Exhibit Number 421?
A. That's correct.
Q. Okay. And you said the strength was excellent, I believe, of the initial prototype, but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
A. Yes.
Q. And it was -- knot slippage was such that it was determined that the 100 percent ultra-high molecular weight polyethylene suture prototype wasn't suitable to be developed?
A. That's correct. Yes.
Q. Okay. Ultra-high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively).
Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

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A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?

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MR. SOFFEN: Objection; asked and answered. You've asked him the same thing multiple times. But you can answer.
A. I've lost count, it's been so many times, but the answer again is yes.
Q. Okay. And Dr. Burkhart said that was a killer idea?
A. What was a killer idea?
Q. The killer idea was that your idea of adding PED -- PET -- I'm sorry. I'll rephrase that question.
Did Dr. Burkhart say that your idea to braid PET with the ultra-high molecular weight polyethylene to improve knot security was a killer idea?
A. Yes.
Q. Okay. And then you said you had Pearsalls manufacture a prototype that had PET and ultra-high molecular weight polyethylene braided?
A. Yes.
Q. And you tested that prototype?
A. Yes.
Q. And you said that that prototype had good knot strength?
A. Correct.
Q. And the prototype of PET braided with ultra-high molecular weight polyethylene had good knot security?

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A. Yes.
Q. And the prototype of PET and ultra-high molecular weight polyethylene braided together also had good tensile strength?
A. Yes.
Q. And after you tested this second prototype, if you will, of the PET braided with ultra-high molecular weight polyethylene, was then the decision made to pursue trying to commercially develop this idea?
A. Yes.
Q. Did you -- when you made -- Who made the decision to go forward and try to commercialize this idea?
A. Myself and Reinhold, surgeons that we collaborated with, marketing people. You know, it wasn't just myself.
Q. Okay. Was this prototype that had the PET braided with the ultra-high molecular weight polyethylene, was it -- did it have a coating on it?
A. Yes.
Q. It did?
A. (Witness nods head affirmatively).
Q. And what was the coating?
A. I forget the name. It's like an MED2174s.
Q. That was on the prototype?
A. Which prototype are you referring to now?

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Q. I'm talking about the --
A. The second prototype with the PET?
Q. Correct.
A. Yes.
Q. The second prototype that had the coating on it?
A. Yes.
Q. And was that part of your initial idea, or was that -- because I thought you said your initial idea was to add the PET. Was it also to coat it, or was that something that came later?
A. If you're going to market the product, it needs the coating on it, sir.
Q. Okay. But the prototype that was manufactured that you asked --
A. Most likely, it was coated, because it needed to be as the final product would be marketed.
Q. You said most likely. Do you remember or you don't remember whether the prototype that had the PET and the ultra-high molecular weight polyethylene was coated?
A. I can't tell you for sure that it was at that prototype stage.
Q. Okay. Was this prototype that you had -- after you tested the prototype with PET with ultra-high --
A. Excuse me. I want to change that.
Q. Okay.

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A. I never got samples of constructions from Pearsalls without a coating unless I specifically asked for it not to be coated. So there's a very high probability that the suture came as -- the second prototype -- as coated.
Q. That was standard for them to coat it, in other words?
A. Yes.
Q. Okay. So the initial prototype that was ultra-high molecular weight polyethylene, did you ask for that not to be coated?
A. No.
Q. So chances are that that one was coated?
A. Quite possibly.
Q. After you tested the prototype of PET and ultra-high molecular weight polyethylene braided together, did you believe that it would then work as a suture?
A. Yes.
Q. Okay. Is there anything else you think you needed to do in order to determine whether it would work as a suture?
A. Yes.
Q. What did you need to do?
A. Biocompatibility toxicity testing, bioburden levels, all the design control GNP items that need to be

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1 decitex?
2 A. No. No, I can't remember that.
3 Q. Do you recall evaluating any samples that had
4 Dyneema 400 denier or higher?
5 A. No.
6 Q. Do you think you did or you just don't recall?
7 A. I received -- I'm sure I received the samples.
8 What I did with them, I don't recall.
9 Q. Okay. How long -- how much before this letter do
10 you think you came up with the idea to use the ultra-high
11 molecular weight polyethylene with PET blended together?
12 A. Whatever the Chicago National Sales Meeting was.
13 The flight just before the start date would be the time
14 that I came up with the idea. I don't know what that time
15 is. I just remember the circumstance.
16 Q. You say Chicago National Sales Meeting?
17 A. That's correct.
18 Q. Is that Arthrex National Sales Meeting?
19 A. Yes.
20 Q. Was that a meeting with all the Arthrex sales
21 reps.?
22 A. That's correct.
23 Q. And it was sometime before the July -- It was the
24 meeting before the July 10, 19 -- I'm sorry. The meeting
25 where you came up with the idea was the meeting before the

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1 July 10th, 1998 date on this letter?
2 A. Yes.
3 Q. I show you DePuy Mitek Exhibit 324. Do you
4 recognize Exhibit 324 as a letter from you to Mr. Hallett?
5 A. I don't recall the letter, but I recognize my
6 name and the contact person. But the specific
7 circumstances of the letter, I don't remember.
8 Q. Based on your prior testimony, is it then true
9 that this letter was after you came up with the idea and
10 after you evaluated the prototype?
11 A. Yes. After I came up with the idea, yes.
12 Q. Okay. Was this letter sent before or after you
13 came up with the -- I'm sorry. Was this November 16th,
14 1998 letter sent before or after you came up with the --
15 Sorry. I will rephrase the question.
16 Was the November 16th, 1998 letter, Exhibit 324,
17 sent before or after you evaluated the prototype of
18 ultra-high molecular weight polyethylene braided with PET?
19 A. I don't recall.
20 Q. When you had the prototype of PET and ultra-high
21 molecular weight polyethylene made, do you know if
22 Pearsalls specifically made that or if they just pulled it
23 off their line from something else?
24 A. I'm sure they made it.
25 Q. They specifically made it?

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1 A. Yes.
2 Q. It's not like they had a product that they could
3 just give to you?
4 A. No.
5 Q. In your letter, you say you tested the samples of
6 Dyneema. Do you see that?
7 A. Yes.
8 Q. And then you say, "Can you build a 25 percent
9 Dyneema/75 percent polyester blend in Size 2 that is very
10 flexible (like the existing suture or the Ethicon sample)
11 and send it to me to test"; do you see that?
12 A. Yes.
13 Q. Does that Ethicon sample, does that refer to an
14 Ethibond?
15 A. Yes.
16 Q. And you say, "If we get the" -- "If we can get
17 this blend correct, we will have a terrific advancement in
18 suture for our soft tissue anchors"; do you see that?
19 A. Yes.
20 Q. What did you mean by that?
21 MR. SOFFEN: Objection; vague. It states what it
22 states. What's the question?
23 Q. Do you understand the question?
24 A. I'm not sure what -- what you're asking.
25 Q. I would like to know what you mean by in your

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1 letter when you said, "If we can get this blend correct."
2 You asked them for a 25 percent Dyneema/75 percent
3 polyester blend in Size 2 that's very flexible. And then
4 you said, "If we can get this blend correct, we will have
5 a terrific advancement."
6 What did you mean by "If we can get this blend
7 correct"?
8 A. The optimization of the two materials. If you
9 had the knot strength, loop security, and tensile
10 strength, as well as the tactile feel of the suture all
11 superior to what was on the market, then it would be a
12 superior product.
13 Q. Wait a second. You said optimization of two
14 materials.
15 A. (Witness nods head affirmatively).
16 Q. At this point in time, November 1998, were you
17 trying to vary the amount and type of the Dyneema and
18 polyester in the braid in order to get the best
19 properties?
20 A. During -- during the -- during that period of
21 time, yes.
22 Q. So you were balancing off the properties of each
23 material to try to get the optimum properties --
24 A. Tensile strength.
25 Q. To get the optimum tensile strength?

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A. (Witness nods head affirmatively).
Q. What about knot security?
A. Yes.
Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
A. Yes.
Q. Any other properties? Knot tiedown?
A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
Q. So you were varying type and proportion of the materials to optimize all these properties in the product?
A. Yes.
Q. Were the product samples that were being made at this time in November of 1998, around this time, were they being made on a carrier braid machine?
A. Yes.
Q. I show you DePuy Mitek Exhibit 325. It's a letter dated November 16th, 1998 from Mr. Hallett to you. Do you see that?
A. Yes.
Q. Do you recall receiving this letter?
A. No.
Q. It says -- Mr. Hallett says in the letter, "Please find enclosed a matrix of information of the

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samples that you took with you on your visit to Pearsalls. I will endeavor to proceed with the existing trial to match the US2 Excel Braid made by Ethicon, in polyester construction." Do you see that?
A. Yes.
Q. Did you pick up the samples from Pearsalls that are mentioned in this --
A. I don't recall.
Q. Do you recall whether they were actually -- Do you recall going over to Pearsalls and having them actually make samples while you were there?
A. Yes.
Q. And were these samples -- These aren't samples they pulled off the line? These are samples where they took yarns and braided them according to what you guys were considering?
A. Repeat the question again.
Q. Sure. I'm just trying to get the sense of whether the samples that you picked up while you were at Pearsalls that you saw being made, were they -- was it an existing product they were picking up off the product line, or was this -- you know -- yarns that were selected and braided and going through the manufacturing process that you particularly picked out?
A. The latter.

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Q. Do you see under the yarns the first one is Dyneema?
A. Yes.
Q. And is has a DT number. Do you see that?
A. DT.
Q. Dt-no. Does that stand for DT number?
A. Where -- where do you see DT?
Q. The second column.
A. At the top as the heading, yes.
Q. Okay. Are you familiar that Pearsalls uses the terminology DT number for samples?
A. I don't recall what they use.
Q. You don't recall? Okay.
Was it the first sample -- Do you see where the first one is Dyneema and the second ones are Polys, the second through fourth are Poly/Dyneema? Do you see that?
A. Yes.
Q. Was the first sample of yarn here all Dyneema?
A. Evidently.
Q. Do you see in the second through the fourth yarns were a braided blend of Polyethylene and Dyneema?
A. Yes.
Q. Do you see the straight pull column?
A. Yes.
Q. I'm sorry. I may have misspoke.

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The second through fourth yarns that are listed, the Poly/Dyneema, is that -- are they Polyester and Dyneema?
A. Yes.
Q. Not polyethylene and Dyneema?
A. It's ultra-high molecular weight polyethylene and PET.
Q. Okay. Do you see the column straight pull?
A. Yes.
Q. Do you know what that means?
A. Testing that they did in their lab with their tensile test machine in kilograms.
Q. Is that with a knot or without a knot?
A. That's without a knot.
Q. Okay. And do you see how the Dyneema one was 23.12 kilograms?
A. Yes.
Q. And Poly/Dyneemas were on the order of 34 to 36 kilograms?
A. Yes.
Q. Do you know why the difference in strength between the Dyneema one and the other ones?
A. You can't tell by looking at this report why there's a difference.
Q. And you don't remember?

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Q. Okay. I show you DePuy Mitek Exhibit 164. Do you recognize Exhibit 164 as a letter from Mr. Hallett to you?
A. Yes.
Q. And did you receive Exhibit 164 on October 19th, 2000?
A. Evidently so.
Q. It says the subject is Polyester-Dyneema Braid. Do you see that?
A. Yes.
Q. And then it says, "Dear Don: Please find enclosed four DT trials samples for your inspection. These have been made using Polyester/Dyneema mixed either in the core -- I'm sorry -- mixed either in the cover or straight core to match US2. I have set up below a matrix of how each was made and the results for your information." Do you see that?
A. Yes.
Q. And the first sample is the DT PA23 sample. Do you see that?
A. Yes.
Q. And if you go down to the cover, it was 16 carriers in use each with one end of 138 d'tex Polyester per carrier. Do you see that?
A. Mmm-hmm (affirmative).

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Q. So the first sample of DT PA23 had a cover that was all polyester; right?
A. Yes.
Q. And is this letter part of the development of FiberWire? It was sent to you in connection with the development of FiberWire?
A. Yes.
Q. If you turn over to the next page, the second sample is DT PA25. And if you look at the cover construction, it was 16 carriers in use, 8 carriers with one end of 113 polyester, 8 carriers with one end of 110 Dyneema. Do you see that?
A. Yes.
Q. So the PA25 had a cover that was a Polyester/Dyneema blend?
A. Correct.
Q. The DT PA26, the construction of that cover was 16 carriers in use, 8 carriers with one end of 113 polyester, 8 carriers with one end of 110 Dyneema. Do you see that?
A. Yes.
Q. So the DT PA26 had a Polyester/Dyneema braid construction in the cover?
A. Correct.
Q. And the DT PA27 had a cover of 16 carriers in

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use, 16 carriers with one end of 113 polyester per carrier. Do you see that?
A. Yes.
Q. So the DT PA27 had a polyester braided cover; right?
A. Yes.
Q. Okay. Now if you look at the knot pull strength of each, of the DT PA23, which was a polyester cover, had a 10.35 at the finish stage of knot pull?
A. Yes.
Q. And the DT PA25 had a knot pull at the center stage of 11.95?
A. Yes.
Q. Do you know what the finish stage is?
A. Yes.
Q. What is the finish stage?
A. After coating.
Q. Okay. And the DT PA26 had a knot pull of 12.87; do you see that?
A. Yes.
Q. And the DT PA27 had a knot pull at finish of 8.04. Do you see that?
A. Yes.
Q. So if you look back and look at the numbers, the first one, the DT PA23 was the polyester cover braid, and

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its knot strength at finish was less than the DT PA25 and DT PA26; correct?
A. Yes.
Q. And DT PA27 was also a polyester cover, and its knot strength at finish stage was less than that of DT PA25 and 26; right?
A. Yes.
Q. Do you know why the DT PA23 and PA 27 samples had lower knot pull strength at the finish stage than DT PA25 and DT PA26?
A. Because there was no Dyneema in the jacket or cover.
Q. And you say that the finish stage was after coating, so all these products had the -- I'm sorry -- so you said the finish stage was after coating, so the DT PA23, 25, 26, and 27 all had coating on it?
A. Yes.
Q. They had the same coating?
A. Yes.
Q. They went through the same coating processes?
A. Yes.
Q. If you look at the d'tex of the Dyneema yarn that was used in these prototypes, it was -- in the cover, the DT PA25 had 110 Dyneema, and the DT PA26 also had 110 Dyneema in the cover? Do you see that?

Q. You're sure you did?
A. Yes.
Q. And what did you review it for?
A. Accuracy, to be sure it covered as much of a claim area as possible.
Q. Okay. Do you recall having any discussions with an attorney that this patent -- patent Exhibit 423 was not accurate?
A. I don't recall that, no.
Q. Do you recall asking an attorney to change anything in Exhibit 423 and having them say no?
A. I don't know. I don't recall.
Q. And do you see how on the front of Exhibit 423, if you look on the first page, it says the Agent, Attorney or Firm, do you see where it says Dickstein, Shapiro, Morin & Oshinsky, LLP; do you see that?
A. Yes.
Q. Do you recall working with attorneys from Dickstein, Shapiro, Morin & Oshinsky in preparing this application?
A. Yes.
Q. Do you recall working with Mr. Soffen in preparing this patent application that became the '423 patent?
A. Yes.



Q. Is Mr. Soffen generally the person you've worked with in preparing patent -- patent applications?
A. He's one of them, yes.
Q. Okay. And how about Mr. McGee?
A. Yes.
Q. Okay. Do you have an understanding that in providing a description of your invention, that the invention should be sufficiently described so that someone skilled in the art could make it?
A. Yes.
Q. Okay. If I could turn to paragraph -- the text beginning on Page ARM 286, the second paragraph, the description of the related art. Do you see that?
A. Yes.
Q. It says, "Suture strength is an important consideration in surgical suture material." Do you agree with that?
A. Yes.
Q. It says, "One of the strongest materials currently formed into elongated strands is an ultra-high molecular long chain weight polyethylene typically used for fishing lines and the like which is sold under the trade names Dyneema or Spectra." Do you agree with that?
A. Yes.
Q. It says, "However, this material, while much



stronger than ordinary surgical suture, does not have acceptable knot tiedown characteristics for use in surgical applications." Do you see that?
A. Yes.
Q. Do you agree with that?
A. Yes.
Q. Do you see the reference to knot tiedown?
A. Yes.
Q. Is that reference to knot tiedown what we referred to this morning as knot tiedown as you described it?
A. It's one of the items we referred to, yes.
Q. And how you defined it this morning, is -- are you using that same definition here?
A. Yes.
Q. Okay. If you go on the front page of this document, it notes Patent Documents -- U.S. Patent Documents References Cited; do you see that?
A. Yes.
Q. And there's a section of Foreign Patent Documents and Other Publications. Do you see that?
A. Mmm-hmm (affirmative). Yes.
Q. Do you recall whether you asked for any fishing line products to be disclosed to the patent office that used ultra-high molecular weight polyethylene?



A. Don't recall.
Q. Go to the Detailed Description of the Preferred Embodiments. Do you see that? It begins on Column 2.
A. Yes.
Q. It says, "Referring to FIG. 1, a scanning electron micrograph of a length of suture 2 according to the present invention is shown."
A. Excuse me. I'd like to interrupt you --
Q. Sure.
A. -- on one of your comments. I want to be sure I get that correct. The -- When you said whether I specifically asked for a fishing line or fishing line patents to be looked at --
Q. I didn't say patent. I said products.
A. Products? The key word would have been put in for the materials used, and if those then had a hit, if you will, with the fishing line, then that patent would have come up.
Q. Right. But I'm just talking about products like -- that were on the market like fishing line products.
A. No. No. That was --
Q. Like the one Pearsalls made.
A. No, we didn't look at Spider Wire or other fishing lines.